Products Approved For Additional Indication (DCA 223 – 24 DECEMBER 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**CLEXANE 6000/0.6ML ANTI-XA IU PREFILLED SYRINGE FOR INJECTION** (ENOXAPARIN SODIUM 60MG /0.6ML)	• *Treatment of acute ST-segment elevation myocardial infarction in combination with a thrombolytic agent in patients eligible or not for subsequent coronary angioplasty.*	**Sanofi-Aventis (M) Sdn Bhd 8th floor, PNB damansara No 19, Lrg Dungun Damansara Heights 50490 Kuala Lumpur**
	1.2	**CLEXANE 8000/0.8ML ANTI-XA IU PREFILLED SYRINGE FOR INJECTION** (ENOXAPARIN SODIUM 80MG /0.8ML)		
	1.3	**CLEXANE 10000/1ML ANTI-XA IU PREFILLED SYRINGE FOR INJECTION** (ENOXAPARIN SODIUM		

		100MG/ 1ML)		
2.0	2.1	**ACLASTA SOLUTION FOR INFUSION 5MG/100ML** (ZOLEDRONIC ACID MONOHYDRATE 5.33MG/100ML (5MG ZOLEDRONIC ACID ANHYDROUS))	• *Prevention of osteoporosis in postmenopausal women at increased risk of fracture.*	**Novartis Corporation (Malaysia) Sdn Bhd Level 15, CREST, 3 Two Square No. 2, Jalan 19/1 46300 Petaling Jaya, Selangor**
3.0	3.1 3.2	**SEROQUEL XR EXTENDED RELEASE TABLET 50MG** (QUETIAPINE FUMARATE 57.56MG (86.86% QUETIAPINE FREE BASE) **SEROQUEL XR EXTENDED RELEASE TABLET 200MG** (QUETIAPINE FUMARATE	• *Seroquel XR is indicated for the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex.* • *The efficacy of SEROQUEL XR in bipolar disorder was established, in part, on the basis of extrapolation from the established effectiveness of SEROQUEL [see Clinical Efficacy (in the package insert)].* *Posology* • *Maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex.* • *While there is no body of evidence available to specifically address how long the patient treated with Seroquel XR should remain on it, maintenance of efficacy in Bipolar I Disorder was demonstrated with Seroquel (administered twice daily totaling 400 to 800 mg per day) as adjunct therapy to lithium or divalproex.* • *Generally, in the maintenance phase, patients continued on the same dose which they*	**AstraZeneca Sdn Bhd Wisma Prisma 17 Jalan Sri Semantan Satu Damansara Heights 50490 Kuala Lumpur**

	3.3 3.4	230.26MG (86.86% QUETIAPINE FREE BASE) **SEROQUEL XR EXTENDED RELEASE TABLET 300MG** (QUETIAPINE FUMARATE 345.38MG (86.86% QUETIAPINE FREE BASE) **SEROQUEL XR EXTENDED RELEASE TABLET 400MG** (QUETIAPINE FUMARATE 460.50MG (86.86% QUETIAPINE FREE BASE)	*were stabilized during the stabilization phase [see Clinical Efficacy (in the package insert)].* • *Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment [see Clinical Efficacy (in the package insert)].* *Pharmacological Properties – Clinical Efficacy* • *Maintenance Therapy: Study 126 + Study 127 [2 placebo-controlled trials in patients (n = 1326) in the maintenance treatment of Bipolar I disorders]*	

Products Approved For Additional Indication (DCA 222 – 17 NOVEMBER 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**ISENTRESS 400MG TABLET** (Raltegravir Potassium 434.4mg equivalent to raltegravir (free phenol) 400mg)	• *ISENTRESS in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in adult patients.* • *This indication is based on analyses of plasma HIV-1 RNA levels up through 48 weeks in three double blind controlled studies of ISENTRESS. Two of these studies were conducted in clinically advanced, 3-class antiretroviral (NNRTI, NRTI, PI) treatment-experienced adults and one was conducted in treatment-naïve adults.* • *The safety and efficacy of ISENTRESS have not been established in pediatric patients.*	**Merck Sharp & Dohme (I.A) Corp. Malaysia Branch T2-9, Jaya 33,No. 3 (Lot 33), Jalan Semangat Seksyen 13 46100 Petaling Jaya, Selangor**
2.0	2.1	**ERBITUX 5MG/ML SOLUTION FOR INFUSION** (Cetuximab 5mg/ml)	❖ *Erbitux® is indicated for the treatment of patients with squamous cell cancer of the head and neck* • *in combination with platinum-based chemotherapy for recurrent and/or metastatic disease* ➢ *And the full indication for squamous cell cancer of the head and neck becomes:* ❖ *Erbitux® is indicated for the treatment of patients with squamous cell cancer of the head and neck* • *in combination with radiation therapy for locally advanced disease* • *in combination with platinum-based chemotherapy for recurrent and/or metastatic disease*	**Merck Sdn Bhd Level 3, Menara Sunway Annexe, Jalan Lagoon Timur, Bandar Sunway, 46150 Petaling Jaya Selangor**
3.0	3.1	**ERBITUX 5MG/ML SOLUTION FOR INFUSION**	❖ *Erbitux® is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS* wild-type metastatic colorectal*	**Merck Sdn Bhd Level 3, Menara Sunway Annexe, Jalan Lagoon**

		(Cetuximab 5mg/ml)	*cancer* • *in combination with chemotherapy* • *as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.*	**Timur, Bandar Sunway, 46150 Petaling Jaya, Selangor**
4.0	4.1 4.2 4.3	**ALPHANATE 1000 IU INJECTION** (Factor VIII Correction 1000IU) **ALPHANATE 500 IU INJECTION** (Factor VIII Correction 400-600IU/vial) **ALPHANATE 250 IU INJECTION** (Factor VIII Correction 200-300IU/VL	❖ *Von Willebrand Disease (vWD)* *Antihemophilic Factor/von Willebrand Factor Complex (Human), Alphanate®, is also indicated for surgical and/or invasive procedure in patients with von Willebrand Disease (vWD), in whom desmopressin (DDAVP*) is either ineffective or contraindicated, except Type 3 patients undergoing major surgery.*	**Grifols Malaysia Sdn Bhd Suite 908, Menara PJ, Amcorp Trade Centre, 18, Jalan Persiaran Barat, 46050 Petaling Jaya, Selangor**

Products Approved For Additional Indication (DCA 221 – 29 OKTOBER 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2 1.3	**Concor 2.5mg Tablet** (Bisoprolol Fumarate 2.5mg) **Concor 5 Film Coated Tablet** (Bisoprolol Fumarate 5mg) **Concor 10 Film-Coated Tablet** (Bisoprolol Fumarate 10mg)	*-Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.* *Posology* ❖ *Treatment of stable chronic heart failure* • *Standard treatment of CHF consists of an ACE inhibitor (or an angiotensin receptor blocker in case of intolerance to ACE inhibitors), a beta-blocker, diuretics, and when appropriate cardiac glycosides. The initiation of treatment of stable chronic heart failure with Concor necessitates a special titration phase.* • *Precondition for treatment with bisoprolol is stable chronic heart failure without acute failure. It is recommended that the treating physician be experienced in the management of chronic heart failure.* • *The treatment of stable chronic heart failure with bisoprolol is initiated according to the following titration scheme, individual adaption may be necessary depending on how well the patient tolerates each dose, i.e. the dose is to be increased only, if the previous dose is well tolerated.* • *The maximum recommended dose is 10mg bisoprolol hemifumarate once daily. Close monitoring of vital signs (blood pressure, heart rate) and symptoms of worsening heart failure is recommended during the titration phase. Symptoms may already occur within the first day after initiating therapy.* ❖ *Treatment modification* • *If during the titration phase or thereafter, transient worsening of heart failure, hypotension or bradycardia occurs, reconsideration of the dosage of concomitant medication is recommended. It may also be necessary to temporarily lower the dose of bisoprolol or to consider discontinuation. The reintroduction and/ or uptitration of bisoprolol should always be considered when the patient becomes stable again.* ❖ *Duration of treatment* • *Treatment with Concor is generally a long-term therapy.* • *The treatment may be interrupted if necessary and reintroduced as appropriate.*	**MERCK SDN. BHD. LEVEL 3, MENARA SUNWAY ANNEXE JALAN LAGOON TIMUR, BANDAR SUNWAY 46150 PETALING JAYA, SELANGOR, MALAYSIA**

Products Approved For Additional Indication (DCA 220 – 01 OKTOBER 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**PRECEDEX** (118mcg dexmedetomidine hydrochloride equivqlent to 100 mcg dexmedetomidine base)	❖ *Precedex is indicated for sedation of non-intubated patients prior to and/ or during surgical and other procedures.* *Posology* ❖ *Dosing Guidelines* • *Precedex dosing should be individualized and titrated to the desired clinical response.* • *Dexmedetomidine is not indicated for infusions lasting longer than 24 hours.* • *Precedex should be administered using a controlled infusion device.* ❖ *Dosage Adjustment* • *Due to possible pharmacodynamic interactions, a reduction in dosage of Precedex or other concomitant anesthetics, sedatives, hypnotics or opioids may be required when co-administered.* • *Dosage reductions may need to be considered for patients with renal or hepatic impairment, and geriatric patients.*	**HOSPIRA MALAYSIA SDN BHD** **SUITE 201, 1ST FLOOR, WISMA GLOMAC 3,** **KOMPLEKS KELANA CENTRE POINT,** **NO. 3, JALAN SS 7/19** **47301 PETALING JAYA** **SELANGOR MALAYSIA**

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Products Approved For Additional Indication (DCA 212– 29 Januari 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**VIGAMOX 0.5% EYE DROP** (Moxifloxacin Hcl)	❖ **Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required)** ❖ **Posology:** **For Preoperative and postoperative sterilization: Usually, instill one drop in the affected eye(s) 5 times per day before operation, and 3 times per day after operation.**	Alcon Laboratories (Malaysia) Sdn. Bhd. No. 1001A & 1001D, 9th Floor Wisma Glomac 3 Kompleks Kelana Centre Point No. 3, Jalan SS7/19, Kelana Jaya 47301 Petaling Jaya Selangor
2.	2.1	**NASONEX AQUEOUS NASAL SPRAY 0.05%** (Mometasone Furoate 0.5mg/g as monohydrate)	❖ **Nasonex Aqueous Nasal Spray is indicated for the treatment of symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.** ❖ **Posology:** **Adults(including geriatric patients) and adolescents 12 years of age or older:** **The usual recommended dose for acute rhinosinusitis is two actuations (50mcg/actuation) in each nostril twice daily (total daily dose of 400mcg). If no improvement is seen after 15 days of twice daily administration, alternative therapies should be considered. If symptoms worsen during treatment, the patient should be advised to consult their physician.**	Schering-Plough Sdn. Bhd Level 12, Wisma UOA Damansara II No. 6, Jalan Changkat Semantan Damansara Heights 50490 Kuala Lumpur Wilayah Persekutuan

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.	3.1	**ALIMTA 500MG INJECTION** (713mg pemetrexed disodium heptahydrate equivalent to pemetrexed free acid 500mg)	❖ **Non-small cell lung cancer:** ❖ **ALIMTA in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.** ❖ **ALIMTA is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.** ❖ **Posology:** **ALIMTA must only be administered under the supervision of a physician qualified in the use of anti-cancer chemotherapy.** ❖ **The ALIMTA solution must be prepared according to the instructions provided in section 6.6 {in the package insert}.** ❖ **<u>ALIMTA in combination with cisplatin</u>: The recommended dose of ALIMTA is 500 mg/m^2 of body surface area (BSA) administered as an intravenous infusion over 10 minutes on the first day of each 21-day cycle. The recommended dose of cisplatin is 75mg/m^2 BSA infused over two hours approximately 30 minutes after completion of the permetrexed infusion on the first day of each 21-day cycle. <u>Patients must receive adequate anti-emetic treatment and appropriate hydration prior to and/or after receiving cisplatin</u> (See also cisplatin product insert for specific dosing advice)**	ELI LILLY (MALAYSIA) SDN. BHD. UNIT 18.1, LEVEL 18, CP TOWER NO. 11, JALAN 16/11 PUSAT DAGANG SEKSYEN 16 46350 PETALING JAYA SELANGOR
	3.2	**ALIMTA 100MG INJECTION** (151.7mg pemetrexed disodium heptahydrate equivalent to pemetrexed free acid 100mg)		

			❖ **ALIMTA as single agent: In patients treated for non-small cell lung cancer after prior chemotherapy, the recommended dose of ALIMTA is 500mg/m^2 BSA administered as an intravenous infusion over 10 minutes on the first day of each 21-day cycle.** ❖ **<u>Premedication regimen:</u>** **To reduce the incidence and severity of skin reactions, a corticosteroid should be given the day prior to, on the day of, and the day after pemetrexed administration. The corticosteroid should be equivalent to 4 mg of dexamethasone administered orally twice a day (see section 4.4 {in the package insert}).** ❖ **To reduce toxicity, patients treated with pemetrexed must also receive vitamin supplementation (see section 4.4 {in the package insert}). Patients must take oral folic acid or a multivitamin containing folic acid (350 to 1000 micrograms) on a daily basis. At least five doses of folic acid must be taken during the seven days preceding the first dose of pemetrexed, and dosing must continue during the full course of therapy and for 21 days after the last dose of pemetrexed. Patients must also receive an intramuscular injection of vitamin B12 (1000 micrograms) in the week preceding the first dose of pemetrexed and once every three cycles thereafter. Subsequent vitamin B12 injections may be given on the same day as pemetrexed.**	

			❖ **<u>Monitoring:</u>** **Patients receiving pemetrexed should be monitored before each dose with a complete blood count, including a differential white cell count (WCC) and platelet count. Prior to each chemotherapy administration, blood chemistry tests should be collected to evaluate renal and hepatic function. Before the start of any cycle of chemotherapy, patients are required to have the following: Absolute Neutrophil Count (ANC) should be ≥1500 cells/mm^3 and platelets should be ≥100,000 cells/mm^3.** ❖ **Creatinine clearance should be ≥45 ml/min.** ❖ **The total bilirubin should be ≤1.5 times upper limit of normal. Alkaline phosphatase (AP), aspartate transaminase (AST or SGOT) and alanine transaminase (ALT or SGPT) should be ≤3 times upper limit of normal. Alkaline phosphatase, AST and ALT ≤5 times upper limit of normal is acceptable if liver has tumour involvement.** ❖ **<u>Dose Adjustments:</u>** **Dose adjustments at the start of a subsequent cycle should be based on nadir haematologic counts or maximum non-haematologic toxicity from the preceding cycle of therapy. Treatment may be delayed to allow sufficient time for recovery. Upon recovery patients should be retreated using the guidelines in Tables 1, 2 and 3, which are applicable for ALIMTA used as a single agent or in combination with Cisplatin.**	

Table 1 - Dose Modification Table for ALIMTA (as single agent or in combination) And Cisplatin-Haematologic Toxicities	
Nadir ANC <500/mm^3 and nadir platelets ≥50,000/mm^3	**75% of previous dose (both ALIMTA and cisplatin).**
Nadir platelets <50,000/mm^3 regardless of nadir ANC	**75% of previous dose (both ALIMTA and cisplatin).**
Nadir platelets <50,000/mm^3 with bleeding[a], regardless of nadir ANC	**50% of previous dose (both drugs).**

[a] These criteria meet the CTC version 2.0 (NCI 1998) definition of CTC Grade 2 bleeding.

- **If patients develop non-haematologic toxicities ≥Grade 3 (excluding neurotoxicity), ALIMTA should be withheld until resolution to less than or equal to the patient's pre-therapy value. Treatment should be resumed according to the guidelines in Table 2.**

Table 2 - Dose Modification Table for ALIMTA (as single agent or in combination) and Cisplatin-Non-haematologic Toxicities[a,b]		
	Dose of ALIMTA (mg/m^2)	Dose of cisplatin (mg/m^2)
Any Grade 3 or 4 toxicities except mucositis	**75% of previous dose**	**75% of previous dose**
Any diarrhoea requiring hospitalisation (irrespective of grade) or grade 3 or 4 diarrhoea	**75% of previous dose**	**75% of previous dose**
Grade 3 or 4 mucositis	**50% of previous dose**	**50% of previous dose**

[a] National Cancer Institute Common Toxicity Criteria (CTC)
[b] Excluding neurotoxicity

- **In the event of neurotoxicity, the recommended dose adjustment for ALIMTA and cisplatin is documented in Table 3. Patients should discontinue therapy if Grade 3 or 4 neurotoxicity is observed.**

Table 3 - Dose Modification Table for ALIMTA (as single agent or in combination) And Cisplatin-Neurotoxicity		
CTC* Grade	Dose of ALIMTA (mg/m^2)	Dose of cisplatin (mg/m^2)
0-1	**100% of previous dose**	**100% of previous dose**
2	**100% of previous dose**	**50% of previous dose**

Common Toxicity Criteria (CTC)

- **Treatment with ALIMTA should be discontinued if a patient experiences any haematologic or non-haematologic Grade 3 or 4 toxicity after 2 dose reductions or immediately if Grade 3 or 4 neurotoxicity is observed.**

- **Elderly: In clinical studies, there has been no indication that patients 65 years of age or older are at increased risk of adverse events compared to patients younger than 65 years old. No dose reductions other than those recommended for all patients are necessary.**

- **Children and adolescents: ALIMTA is not recommended for use in patients under 18 years of age, as safety and efficacy have not been established in this group of patients.**

- **Patients with Renal Impairment (Standard Cockcroft and Gault formula or Glomerular Filtration Rate measured Tc99m-DPTA serum clearance method): Pemetrexed is primarily**

			eliminated unchanged by renal excretion. In clinical studies, patients with creatinine clearance of 45 ml/min required no dose adjustments other than those recommended for all patients. There are insufficient data on the use of pemetrexed in patients with creatinine clearance below 45 ml/min; therefore the use of pemetrexed is not recommended (see section 4.4 {in the package insert}). ❖ **Patients with Hepatic Impairment: No relationships between AST (SGOT), ALT (SGPT), or total bilirubin and pemetrexed pharmacokinetics were identified. However patients with hepatic impairment such as bilirubin >1.5 times the upper limit of normal and/or transaminase >3.0 times the upper limit of normal (hepatic metastases absent) or >5.0 times the upper limit of normal (hepatic metastases present) have not been specifically studied.**	
4.	4.1 4.2 4.3	**ZEMPLAR CAPSULE 1 MCG** (Paricalcitol 1 mcg) **ZEMPLAR CAPSULE 2 MCG** (Paricalcitol 2 mcg) **ZEMPLAR CAPSULE 4 MCG** (Paricalcitol 4 mcg)	❖ **Zemplar capsules are indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency (chronic kidney disease Stage 3 and 4) patients and chronic renal failure (chronic kidney disease Stage 5) patients on hemodialysis or peritoneal dialysis.** ❖ **Posology:** **Chronic kidney disease (CKD) Stage 5:** **Zemplar should be administered three times a week every other day**	ABBOTT LABORATORIES (M) SDN. BHD. NO.22, JALAN PEMAJU U1/15, SECTION U1 HICOM-GLENMARIE INDUSTRIAL PARK 40150 SHAH ALAM SELANGOR

			❖ **Initial Dose** **The initial dose of Zemplar in micrograms is based on a baseline iPTH level (pg/mL)/60[(pmol/L)/7], up to an initial maximum dose of 32 micrograms.** ❖ **Dose Titration** **Sebsequent dosing should be individualized and based on iPTH, serum calcium and phosphorus levels. A suggested dose titration of paricalcitol capsules is based on te following formula:** ***Titration dose (micrograms) = most recent iPTH level (pg/mL) / 60*** ***OR*** ***Titration dose (micrograms) = most recent iPTH level (pg/mL) / 7*** ❖ **Serum calcium and phosphorus level should be closely monitored after initiation, during dose titration periods, and with co-administration of strong P450 3A inhibitors. If an elevated serum calcium or elevated Ca x P is observed and the patient is on a calcium-based phosphate binder, the binder dose may be decreased or witheld, or the patient may be switched to a non-calcium-based phosphate binder.** ❖ **If serum calcium > 11.0 mg/dL ($2.8 mmol^2/L^2$) or Ca x P > 70 mg/dL ($5.6 mmol^2/L^2$) or iPTH ≤ 150pg/mL, the dose should be decreased by 2 to 4 micrograms with respect to that calculated by the most recent iPTH/60(pg/mL) [iPTH/7(pmol/L)]. If further adjustment is required, the dose of paricalcitol capsules should be reduced or interrupted unti these parameters are normalized.**	

			❖ **As iPTH approaches the target (150-300pg/mL), small, individualized dose adjustments may be necessary in order to achieve a stable iPTH. In situations where monitoring of iPTH, Ca or P occurs less frequently than once per week, a more modest initial and dose titration ratio may be warranted.**	
5.	5.1 5.2 5.3	**RAPAMUNE TABLET 1 MG** (Sirolimus 1 mg) **RAPAMUNE TABLET 2 MG** (Sirolimus 2 mg) **RAPAMUNE 1MG/ML ORAL SOLUTION** (Sirolimus 1 mg/ml)	❖ **In patients at high immunologic risk (defined as Black transplant recipients and/or repeat renal transplant recipients who lost a previous allograft for immunologic reason and/or patients with high-panel reactive antibodies [PRA; peak PRA level > 80%]), it is recommended that Rapamune be used in combination with cyclosporine and corticosteroids for the first year following transplantation (see CLINICAL STUDIES, DOSAGE AND ADMINISTRATION). The safety and efficacy of these combinations in high-risk patients have not been adequately studied beyond one year; and it is therefore not recommended. This includes patients with Banff grade III acute rejection or vascular rejection prior to cyclosporine withdrawal, those who are dialysis-dependent, or with serum creatinine > 4.5 mg/dL, black patients, retransplants, multi-organ transplants, patients with high panel of reactive antibodies (SEE CLINICAL STUDIES). Therefore after the first year folowing transplantation, any adjustments to the immunosuppresive regimen should be considered on the basis of the clinical status of the patient.**	WYETH (MALAYSIA) SDN. BHD. T1-12, JAYA 33, NO. 3 (LOT 33), JALAN SEMANGAT, SEKSYEN 13 46100 PETALING JAYA SELANGOR

6.	6.1 6.2 6.3 6.4	**ALVESCO 80 MCG (120PUFF)** (Ciclesonide 80 mcg 0.17% w/w) **ALVESCO 160 MCG (120PUFF)** (Ciclesonide 160 mcg 0.34% w/w) **ALVESCO 80 MCG (60PUFF)** (Ciclesonide 80 mcg 0.17% w/w) **ALVESCO 160 MCG (60PUFF)** (Ciclesonide 160 mcg 0.34% w/w)	❖ **Alvesco is indicated as prophylactic treatment of asthma in adults, adolescents and children over 6 years.** ❖ **Posology:** **The recommended dose range for adults, elderly patients and adolescents over 12 years of age with mild to moderate asthma is 160 to 640mcg per day. In severe asthma, this dose may be increased to 1280mcg per day. The recommended dose range for children over 6 years is 80 to 160 mcg per day.**	DKSH Malaysia Sdn Bhd 74 Jalan Universiti 46200 Petaling Jaya Selangor

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Products Approved For Additional Indication (DCA 213– 19 Februari 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**AVASTIN INJECTION 25MG/ML** (Bevacizumab 25mg/ml)	❖**Advanced and/or metastatic Renal Cell Cancer (mRCC)** ❖**Avastin in combination with interferon alfa-2a is indicated for first-line treatment of patients with advanced and/or metastatic renal cell cancer.**	ROCHE (M) SDN. BHD. 14th. FLOOR, WEST BLOCK WISMA SELANGOR DREDGING, 142, JALAN AMPANG 50450 KUALA LUMPUR WILAYAH PERSEKUTUAN
2.	2.1	**CONCERTA 18 MG EXTENDED – RELEASE TABLET** (18mg Methylphenidate Hydrochloride)	❖**Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adolescents (13 to 17 years of age).** ❖**Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adults (>18 years of age).** ❖**Posology:** **CONCERTA is administered orally once daily. As the effect has been shown to be present 12 hours after dosing, the product should be taken once daily in the morning.** ❖**CONCERTA must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed (see Special Warnings and Special Precautions for Use {in the package insert}).** ❖**CONCERTA may be administered with or without food (see Pharmacokinetic Properties {in the package insert}).**	JOHNSON & JOHNSON SDN BHD LOT 3 & 5, JALAN TANDANG 46050 PETALING JAYA SELANGOR
	2.2	**CONCERTA 27 MG EXTENDED – RELEASE TABLET** (27mg Methylphenidate Hydrochloride)		
	2.3	**CONCERTA 36 MG EXTENDED – RELEASE TABLET** (36mg Methylphenidate Hydrochloride)		
	2.4	**CONCERTA 54 MG EXTENDED – RELEASE TABLET** (54mg Methylphenidate Hydrochloride)		

❖**Patients New to Methylphenidate:**

❖**The recommended starting dose of CONCERTA for patients, who are not currently taking methylphenidate or stimulants other than methylphenidate, is 18 mg once daily for children and adolescents and 18 or 36mg once daily for adults.**

❖**Patients Currently Using Methylphenidate:**

❖**The recommended dose of CONCERTA for patients who are currently taking methylphenidate twice daily or three times daily, at doses of 10 to 60 *mg/day, is provided in the following table:***

Recommended Dose Conversion from Methylphenidate Regimens to CONCERTA

Previous Methylphenidate Daily Dose	Recommended CONCERTA Starting Dose
5mg Methylphenidate twice daily or three times daily	18mg every morning
10mg Methylphenidate twice daily or three times daily	36mg every morning
15mg Methylphenidate twice daily or three times daily	54mg every morning
20mg Methylphenidate twice daily or three times daily	72mg every morning

			❖Clinical judgment should be used when selecting the dose for patients currently taking methylphenidate in other regimens. ❖Dose Titration: ❖Dosage should be individualized according to the needs and responses of the patient. Doses may be increased in 18 mg increments at weekly intervals. Daily dosages above 54mg in children, 72 mg in adolescents, and 108 mg in adults have not been studied and are not recommended. ❖Maintenance/Extended Treatment: ❖The long-term use of methylphenidate has not been systematically evaluated in controlled trials. The physician who elects to use CONCERTA for extended periods in patients with ADHD should periodically re-evaluate the long-term usefulness of the drug for the individual patient with trials off medication to assess the patient's functioning without pharmacotherapy. ❖Dose Reduction and Discontinuation: ❖If paradoxical aggravation of symptoms or other adverse events occur, the dosage should be reduced, or, if necessary, the drug should be discontinued. ❖CHILDREN: ❖Use of CONCERTA in patients under six years of age has not been studied in controlled trials. CONCERTA should not be used in patients under six years old. ❖ELDERLY: ❖Use of CONCERTA in elderly patients over 65 years of age has not been studied in controlled trials.	

Maklumat tambahan indikasi untuk upload pada laman web

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Products Approved For Additional Indication (DCA 214– 26 Mac 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**MABCAMPATH 30MG/ML CONCENTRATE SOLUTION FOR INFUSION** (Alemtuzumab 30mg/ml)	❖**MabCampath is indicated for the treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL).**	BAYER CO. (MALAYSIA) SDN BHD T1-14, JAYA 33 NO. 3, JALAN SEMANGAT SEKSYEN 13 46200 PETALING JAYA SELANGOR
2.	2.1 2.2	**CEREZYME® 200 UNITS INJECTION** (Imiglucerase 212 units*/vial) *Extractable dose of 200 units **CEREZYME® 400 UNITS INJECTION** (Imiglucerase 424 units*/vial) *Extractable dose of 400 units	❖**Cerezyme (imiglucerase) is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease and who exhibit clinically significant non-neurological manifestations of the disease.**	DKSH MALAYSIA SDN BHD 74, JALAN UNIVERSITI 46200 PETALING JAYA SELANGOR
3.	3.1	**IRESSA 250MG** (250mg Gefitinib)	❖**IRESSA is indicated for the treatment of patients with locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC) who have previously received and failed chemotherapy.**	ASTRAZENECA SDN. BHD. GROUND FLOOR, WISMA PRIMA 17, JALAN SEMANTAN SATU 50490 KUALA LUMPUR WILAYAH PERSEKUTUAN

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
4.	4.1	**ACLASTA SOLUTION FOR INFUSION 5 MG/100 ML** (One bottle with 100mL solution contains 5mg zoledronic acid (anhydrous), corresponding to 5.330 zoledronic acid monohydrate)	❖**Treatment of osteoporosis:** **- in post menopausal women to reduce the incidence of hip, vertebral and non-vertebral fractures,** **-in men** **at increased risk of fracture, including those with a recent low-trauma hip fracture.** ❖**Treatment of Paget's disease of bone.** ❖**Posology** ❖ **For the treatment of postmenopausal osteoporosis and osteoporosis in men, the recommended dose is a single intravenous infusion of 5 mg infusion of Aclasta administered once a year.** ❖ **In patients with a recent low-trauma hip fracture, it is recommended to give the Aclasta infusion two or more weeks after hip fracture repair.** ❖ **For the treatment of Paget's disease the recommended dose is a single intravenous infusion of 5 mg Aclasta.** ❖ **Retreatment of Paget's disease: Specific retreatment data are not available. After a single treatment with Aclasta in Paget's disease, an extended remission period is observed in responding patients.** ❖ **Aclasta (5 mg in 100 mL ready to infuse solution) is administered intravenously via a vented infusion line, given at a constant infusion rate. The infusion time must not be less than 15 minutes.** ❖ **Patients must be appropriately hydrated prior to administration of Aclasta. This is especially important for patients receiving diuretic therapy.**	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. LEVEL 15, CREST, 3 TWO SQUARE NO.2, JALAN 19/1, 46300 PETALING JAYA SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			❖**Adequate calcium and vitamin D intake is important in patients with osteoporosis if dietary intake is inadequate.** ❖**Elevated bone turnover is a characteristic of Paget's disease of bone. It is strongly advised that patients with Paget's disease receive the recommended daily allowance of supplemental calcium and vitamin D and this should be ensured during the initial 10 days following Aclasta administration.** ❖**The incidence of post-dose symptoms occurring within the first three days after administration of Aclasta can be reduced with the administration of paracetamol or ibuprofen shortly following Aclasta administration.** ❖**Patients with renal impairment** **-The use of Aclasta in patients with creatinine clearance < 30 mL/min is not recommended due to lack of adequate clinical experience in this population.** ❖**No dose adjustment is necessary in patients with creatinine clearance ≥ 30 mL/min.** ❖**Patients with hepatic impairment** **-No dose adjustment is required.** ❖**Elderly (≥ 65 years)** **-No dose adjustment is necessary since bioavailability, distribution and elimination were similar in elderly patients and younger subjects.** ❖**Children and adolescents** **-Aclasta has not been tested in children and adolescents and therefore should not be used in these age groups.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
5.	5.1	**CORDARONE INJ 150MG (3ML AMP)** (Amiodarone HCl 50mg/ml)	❖**Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.** ❖**Posology** ❖**<u>Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock</u>** ❖**As regards the administration route and in view of the situation in which this indication applies, the use of a central venous catheter is recommended if immediately available; otherwise, the medicinal product may be administered via the peripheral venous route using the largest peripheral vein with the highest flow possible.** ❖**The initial intravenous dose is 300 mg (or 5 mg/kg) diluted in 20 ml of 5% glucose solution and rapidly injected.** ❖**Additional intravenous administration of 150 mg (or 2.5 mg/kg) may be envisaged if ventricular fibrillation persists.** ❖**Do not add any other products to the syringe.**	SANOFI-AVENTIS (MALAYSIA) SDN. BHD. 8TH FLOOR, PNB DAMANSARA NO. 19, LORONG DUNGUN DAMANSARA HEIGHTS 50490 KUALA LUMPUR WILAYAH PERSEKUTUAN
6.	6.1	**GADOVIST 1.0 MMOL/ML (15ML & 30ML)** (Each mL contains 604.72mg of gadobutrol (equivalent to 1.0 mmol gadobutrol containing 157.25mg gadolinium))	❖ **Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesion to classify these lesions as benign or malignant.** **Posology** ❖ **The recommended dose for adults is 0.1ml Gadovist mmol per kilogram body weight (mmol / kg BW). This is equivalent to 0.1ml/kg BW of the 1.0M solution.**	BAYER CO. (MALAYSIA) SDN. BHD. T1-14 JAYA 33 NO.3, JALAN SEMANGAT 46200 PETALING JAYA SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
7.	7.1	**LIPITOR TABLET 10MG** (10mg Crystalline Atorvastatin)	❖**In patients with clinically evident coronary heart disease, atorvastatin is indicated to:** **-reduce the risk of non-fatal myocardial infarction,** **--educe the risk of fatal and non-fatal stroke,** **-reduce the risk of revascularization procedures,** **-reduce the risk of hospitalization for CHF,** **-reduce the risk of angina** ❖**(See Section 5.1 Pharmacodynamic Properties {in the package insert})** ❖**<u>Pediatric Patients (10-17 years of age)</u>** ❖**Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:** **a)LDL-C remains <u>≥</u> 190 mg/dL or** **b)LDL-C remains <u>≥</u> 160 mg/dL and:** **-there is a positive family history of premature cardiovascular disease or** **-two or more other CVD risk factors are present in the pediatric patient.** ❖**<u>POSOLOGY:</u>** ❖**Heterozygous Familial Hypercholesterolemia in Paediatric Patients (10-17 years of age) -** ❖**The recommended starting dose of atorvastatin is 10mg/day; the maximum recommended dose is 20mg/day (doses greater than 20mg have not been studied in this patient population). Doses should be individualized according to the recommended goal of therapy.**	PFIZER (MALAYSIA) SDN. BHD. LEVEL 3 & 4, BANGUNAN PALM GROVE NO. 14, JALAN GLENMARIE, SECTION U1 40150 SHAH ALAM SELANGOR
	7.2	**LIPITOR TABLET 10MG** (20mg Crystalline Atorvastatin)		
	7.3	**LIPITOR TABLET 10MG** (40mg Crystalline Atorvastatin)		
	7.4	**LIPITOR TABLET 10MG** (80mg Crystalline Atorvastatin)		

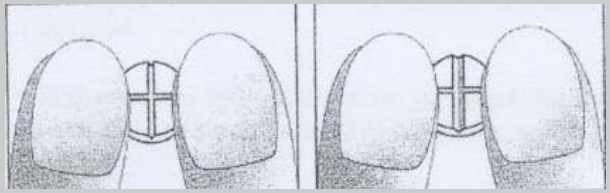
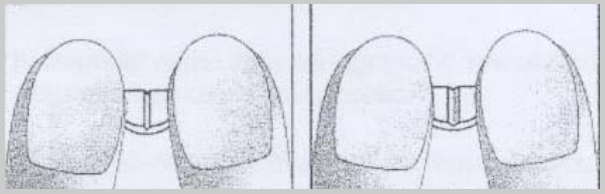
NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			(see section 4.1 Therapeutic indications {in the package insert} and section 5.1 Pharmacodynamic properties {in the package insert}). Adjustments should be made at intervals of 4 weeks or more. **❖ Use in Children (Homozygous Familial Hypercholesterolemia) - Treatment experience in a pediatric population is limited to doses of atorvastatin up to 80mg/day for one year in 8 patients with homozygous FH. No clinical or biochemical abnormalities were reported in these patients.** **❖ <u>Section 5.1 Pharmacodynamic properties – Secondary Prevention of Cardiovascular Events.</u>** **- Treating to New Targets Study (TNT)** **Incremental Decrease in Endpoints Through Aggressive Lipid Lowering Study (IDEAL)** **❖ <u>Section 5.1 Pharmacodynamic properties – Heterozygous Familial Hypercholesterolemia in Paediatric Patients.</u>** **- PROTOCOL 981-147 (a double blind, placebo-controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10-17 years of age)**	
8.	8.1	**AERIUS TABLET** (0.5mg/mL Desloratidine)	❖ **<u>Aerius Syrup 0.5mg/mL</u>** **- AERIUS Syrup are indicated for the rapid relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness.**	SCHERING-PLOUGH SDN BHD LEVEL 12, WISMA UOA DAMANSARA II NO. 6, JALAN CHANGKAT SEMANTAN DAMANSARA HEIGHTS 50490 KUALA LUMPUR WILAYAH PERSEKUTUAN

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			<u>Posology:</u> **❖The prescriber should be aware that most cases of rhinitis below 2 years of age are of infections origin and there are no data supporting the treatment of infectious rhinitis with AERIUS.** **❖Children 6 through 11 years of age: 5 ml (2.5 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria.** **❖Children 1 through 5 years of age: 2.5 ml (1.25 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria.** **❖In adults and adolescents (12 years of age and over): 10 ml (5 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria.** **❖Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			❖**In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during allergen exposure periods.** ❖ **<u>Aerius Tablet 5mg</u>** ❖ **<u>Posology:</u>** ❖ **Adults and Adolescents (12 years of age and older): One AERIUS 5 mg film-coated tablet once a day regardless of mealtime for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria. For oral use.** ❖ **Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during allergen exposure periods.** ❖ **<u>Clinical Pharmacology – Pharmacodynamic properties</u>**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			▪ **In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.**	
9.	9.1	**AVODART SOFT GELATIN CAPSULES** (Dutasteride 0.5mg)	❖ **AVODART in combination with the alpha-blocker tamsulosin is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.** ❖**Posology** ❖ **Adult males (including elderly)** **-AVODART can be administered alone or in combination with the alpha–blocker tamsulosin (0.4mg).** **-The recommended dose of AVODART is one capsule (0.5mg) taken orally once a day. Capsules should be swallowed whole and not chewed or opened, as contact with the capsule contents may result in irritation of the oropharyngeal mucosa.** **- AVODART may be taken with or without food.** **Although an improvement may be observed at an early stage, treatment for at least 6 months may be necessary in order to access objectively whether a satisfactory response to the treatment can be achieved.** **Renal impairment** **The effect of renal impairment on dutasteride pharmacokinetics has not been studied. However, no adjustment in dosage is anticipated for patients with renal impairment.**	GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD. 8TH FLOOR, MENARA LIEN HOE, NO.8, PERSIARAN TROPICANA, 47410 PETALING JAYA, SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			❖**Hepatic Impairment** **-The effect of hepatic impairment on dutasteride pharmacokinetic has not been studied so caution should be used in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the use of dutasteride is contraindicated.**	
10.	10.1	**NEBILET TABLET** (Nebivolol HCl 5.45 mg equivalent to nebivolol 5mg)	❖ **<u>Chronic heart failure (CHF)</u>** - **Treatment of stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients ≥70 years.** ❖ **POSOLOGY:** ❖ **<u>Chronic heart failure (CHF)</u>** **- The treatment of stable chronic heart failure has to be initiated with gradual uptitration of dosage until the optimal individual maintenance dose is reached.** **- Patients should have stable chronic heart failure without acute failure during the past six weeks. It is recommended that the treating physician should be experienced in the management of chronic heart failure.** **- For those patients receiving cardiovascular drug therapy including diuretics and/ or digoxin and/ or ACE inhibitors and/ or angiotensin II antagonists, dosing of these drugs should be stabilized during the past two weeks prior to initiation of Nebilet treatment.**	PHARMAFORTE (MALAYSIA) SDN. BHD. NO. 2, JALAN PJU 3/49 SUNWAY DAMANSARA 47810 PETALING JAYA SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			- The initial uptitration should be done according to the following steps at 1-2 weekly intervals based on patient tolerability: **❖1.25 mg nebivolol, to be increased to 2.5mg nebivolol once daily, then to 5mg once daily and then to 10mg once daily.** **❖The maximum recommended dose is 10mg nebivolol once daily.** **- For a correct breaking of the tablet the below instructions should have to be followed:** **❖Tablet has to be placed onto a flat, hard surface (e.g. table or worktop), with the cross score facing up.** **❖Break the tablet by pushing it with the index fingers of both hands placed along one break-mark (Diagrams 1 and 2).**  **Diagrams 1 and 2: Easy breaking of the Nebivolol 5 mg cross-scored tablet in half**  **Diagrams 3 and 4: Easy breaking of half of the Nebivolol 5mg cross-scored tablet into quarters.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			❖ **Initiation of therapy and every dose should be done under the supervision of an experienced physician over a period of at least 2 hours to ensure that the clinical status (especially as regards blood pressure, heart rate, conduction disturbances, signs of worsening of heart failure) remains stable.** ❖ **Occurrence of adverse events may prevent all patients being treated with the maximum recommended dose. If necessary, the dose reached can also be decreased step by step and reintroduced as appropriate.** ❖ **During the titration phase, in case of worsening of the heart failure or intolerance, it is recommended first to reduce the dose of of nebivolol, or to stop it immediately if necessary (in case of severe hypotension, worsening of the heart failure with acute pulmonary oedema, cardiogenic shock, symptomatic bradycardia or AV block).** ❖ **Treatment of stable chronic heart failure with nebivolol is generally a long-term treatment.** **The treatment with nebivolol is not recommended to be stopped abruptly since this might lead to a transitory worsening of heart failure. If discontinuation is necessary, the dose should be gradually decreased divided into halves weekly.** **Tablets may be taken with meals.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
			- <u>Patients with renal insufficiency</u> **No dose adjustment is required in mild to moderate renal insufficiency since uptitration to the maximum tolerated dose is individually adjusted. There is no experience in patients with severe renal insufficiency (serum creatinine <u>≥</u> 250 µmol/L). Therefore, the use of nebivolol in these patients is not recommended.** **<u>Patients with hepatic insufficiency</u>** **Data in patients with hepatic insufficiency are limited. Therefore the use of Nebilet in these patients is contra-indicated.** **<u>Elderly</u>** **No dose adjustment is required since uptitration to the maximum tolerated dose is individually adjusted.** **<u>Children and adolescents</u>** **No studies have been conducted in children and adolescents. Therefore, use in children and adolescents is not recommended.**	

Maklumat tambahan indikasi untuk upload pada laman web

Year 2009

Products Approved For Additional Indication (DCA 215– 30 April 2009)

<table>
<tr><th>NO</th><th></th><th>PRODUCT (ACTIVE INGREDIENT)</th><th>ADDITIONAL INDICATION</th><th>MARKETING AUTHORIZATION HOLDER</th></tr>
<tr><td>1.</td><td>1.1</td><td>VELCADE (BORTEZOMIB) FOR INJECTION (3.5mg Bortezomib)</td><td>
❖VELCADE (bortezomib) for Injection is indicated for the treatment of patients with multiple myeloma.
❖Velcade (bortezomib) for Injection is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

Posology:

❖Dosage in Previously Untreated Multiple Myeloma

❖VELCADE (bortezomib) is administered as a 3 – 5 second bolus IV injection in combination with oral mephalan and oral prednisone for nine 6-week treatment cycles as shown in Table 1. In Cycles 1 – 4, VELCADE is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In Cycles 5 – 9, VELCADE is administered once weekly (days 1, 8, 22 and 29). At least 72 hours should elapse between consecutive doses of VELCADE.

❖Table 1: Dosage Regimen for Patients with Previously Untreated Multiple Myeloma
<table>
<tr><td colspan="13">Twice Weekly VELCADE (Cycles 1-4)</td></tr>
<tr><td>Week</td><td colspan="5">1</td><td colspan="2">2</td><td>3</td><td>4</td><td colspan="2">5</td><td>6</td></tr>
<tr><td>VELCADE (1.3 mg/m^2)</td><td>Day 1</td><td>--</td><td>--</td><td>Day 4</td><td>Day 8</td><td>Day 11</td><td>rest period</td><td>Day 22</td><td>Day 25</td><td>Day 29</td><td>Day 32</td><td>rest period</td></tr>
<tr><td>Melphalan (9 mg/m^2) Prednisone (60 mg/m^2)</td><td>Day 1</td><td>Day 2</td><td>Day 3</td><td>Day 4</td><td>--</td><td>--</td><td>rest period</td><td>--</td><td>--</td><td>--</td><td>--</td><td>rest period</td></tr>
</table>
</td><td>JANSSEN-CILAG A DIVISION OF JOHNSON & JOHNSON SDN BHD
3RD FLOOR, 3.01, BLOCK B, NO 10, JALAN BERSATU 13/4, 46200 PETALING JAYA, SELANGOR DARUL EHSAN.</td></tr>
</table>

Once Weekly VELCADE (Cycles 5-9 when used in combination with Melphalan and Prednisone)												
Week	1				2		3	4		5		6
VELCADE (1.3 mg/m^2)	Day 1	--	--		Day 8		rest period	Day 22		Day 29		rest period
Melphalan (9 mg/m^2) Prednisone (60 mg/m^2)	Day 1	Day 2	Day 3	Day 4	--	--	rest period	--	--	--	--	rest period

- Dose Modification Guidelines for Combination Therapy with VELCADE, Melphalan & Prednisone
- Prior to initiating any cycle of therapy with VELCADE in combination with melphalan and prednisone:
  - Platelet count should be $\geq$ 70 x 10^9/L and the ANC should be $\geq$ 1.0 x 10^9/L
  - Non-hematological toxicities should have resolved to Grade 1 or baseline
- Table 2: Dose Modifications During Cycles of Combination VELCADE, Melphalan & Prednisone Therapy

Toxicity	Dose modification or delay
Hematological toxicity during a cycle: If prolonged Grade 4 neutropenia or thrombocytopenia, or thrombocytopenia with bleeding is observed in the previous cycle	Consider reduction of the melphalan dose by 25% in the next cycle.
If platelet count $\leq$ 30 x 10^9/L or ANC $\leq$ 0.75 x 10^9/L on a VELCADE dosing day (other than day 1)	Velcade dose should be withheld
If several VELCADE doses in consecutive cycles are withheld due to toxicity	VELCADE dose should be reduced by 1 dose level (from 1.3 mg/m^2 to 1 mg/m^2, or from 1 mg/m^2 to 0.7 mg/m^2)
Grade $\geq$3 non-hematological toxicities	VELCADE therapy should be withheld until symptoms of the toxicity have resolved to Grade 1 or baseline. Then, VELCADE may be reinitiated with one dose level reduction (from 1.3 mg/m^2 to 1 mg/m^2, or from 1 mg/m^2 to 0.7 mg/m^2). For VELCADE-related neuropathic pain and/or peripheral neuropathy, hold and/or modify VELCADE as outlined in Table 3.

- **For information concerning melphalan and prednisone, see manufacturer's prescribing information.**
- **Dosage in Relapsed Multiple Myeloma and Mantle Cell Lymphoma**
- **VELCADE (1.3 mg/m^2/dose) is administered as a 3 to 5 second bolus intravenous injection twice weekly for 2 weeks (Days 1, 4, 8, and 11) followed by a 10-day rest period (Days 12 - 21). For extended therapy of more than 8 cycles, VELCADE may be administered on the standard schedule or on a maintenance schedule of once weekly for 4 weeks (Days 1, 8, 15, and 22) followed by a 13-day rest period (Days 23 to 35). At least 72 hours should elapse between consecutive doses of VELCADE.**
- **Dose Modification Guidelines for Relapsed Multiple Myeloma**
- **VELCADE therapy should be withheld at the onset of any Grade 3 non-hematological or Grade 4 hematological toxicities excluding neuropathy as discussed below (see Special Warnings and Special Precautions for Use). Once the symptoms of the toxicity have resolved, VELCADE therapy may be reinitiated at a 25% reduced dose (1.3 mg/m^2/dose reduced to 1.0 mg/m^2/dose; 1.0 mg/m^2/dose reduced to 0.7 mg/m^2/dose).**
- **For the management of patients who experience VELCADE related neuropathic pain and/or peripheral neuropathy see Table 3. Patients with preexisting severe neuropathy should be treated with VELCADE only after careful risk-benefit assessment.**
- **Table 3: Recommended Dose Modification for Velcade-related Neuropathic Pain and/or Peripheral Sensory or Motor Neuropathy**

Severity of Peripheral Neuropathy Signs and Symptoms	Modification of Dose and Regimen
Grade 1 (paresthesias, weakness and/or loss of reflexes) without pain or loss of function	No action
Grade 1 with pain or Grade 2 (interfering with function but not with activities of daily living)	Reduce Velcade to 1.0 mg/m^2
Grade 2 with pain or Grade 3 (interfering with activities of daily living)	Withhold Velcade therapy until toxicity resolves. When toxicity resolves reinitiate with a reduced dose of Velcade at 0.7 mg/m^2 and change treatment schedule to once per week.
Grade 4 (sensory neuropathy which is disabling or motor neuropathy that is life threatening or leads to paralysis)	Discontinue Velcade

*** Grading based on NCI Common Toxicity Criteria CTCAE v3.0**

			Patients with Renal Impairment: ❖**The pharmacokinetics of VELCADE are not influenced by the degree of renal impairment. Therefore, dosing adjustments of VELCADE are not necessary for patients with renal insufficiency. Since dialysis may reduce VELCADE concentrations, the drug should be administered after the dialysis procedure (see Pharmacokinetic Properties [in the package insert]).** **Patients with Hepatic Impairment:** ❖**Bortezomib is metabolized by liver enzymes and bortezomib's clearance may decrease in patients with hepatic impairment. These patients should be closely monitored for toxicities when treated with Velcade.** **Administration:** ❖**VELCADE is administered as a 3-5 second bolus intravenous injection through a peripheral or central intravenous catheter followed by a flush with 0.9% sodium chloride solution for injection.** ❖**Children (2 to 16 years old)** ❖**The safety and effectiveness of VELCADE in children has not been established.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.	2.1	**Avelox Tablet** (400mg moxifloxacin equivalent to moxifloxacin hydrochloride 436.8mg)	❖**Avelox tablets are indicated for the treatment of adults (≥ 18 years of age) with the following bacterial infections caused by susceptible strains:** ❖**Mild to moderately severe inflammatory pelvic disease (i.e. Infections of the upper female genital tract, including salpingitis and endometritis), without an associated tubo-ovarian or pelvic abscess.** ❖**Avelox 400 mg film-coated tablets are not recommended for monotherapy of mild to moderately severe inflammatory pelvic diseases. Preferably, they should be administered in combination with another suited antibiotic (such as cephalosporin), due to the increasing resistance of Neisseria gonorrheae to moxifloxacin; that is, unless moxifloxacin-resistant Neisseria gonorrheae can be ruled out.** **Posology** ❖**The recommended dose for moxifloxacin is 400mg once daily (1 film-coated tablet or 250ml solution for infusion, respectively) for the above mentioned indications and should not be exceeded.** **Duration of treatment** ❖ **Film-coated tablet:** **Mild to moderately severe inflammatory pelvic diseases: 14 days**	BAYER SCHERING PHARMA BAYER CO. (M) SDN BHD T1-14 JAYA 33, NO 3 JALAN SEMANGAT SEKSYEN 13, 46200 PETALING JAYA SELANGOR.

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.	3.1	**CAELYX CONCENTRATE FOR INFUSION 2MG/ML (20MG/VIAL)** (Doxorubicin Hydrochloride 2mg/ml)	❖**MULTIPLE MYELOMA** **CAELYX is indicated in combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.** **Posology** ❖**Multiple myeloma: Caelyx is administered at 30mg/m^2 on day 4 of the bortezomib 3 week regimen as a 1 hour infusion administered immediately after the bortezomib infusion. The bortezomib regimen consists of 1.3mg/m^2 on days 1, 4, 8, and 11 every 3 weeks. The dose should be repeated as long as patients respond satisfactorily and tolerate treatment.** ❖**For doses < 90mg: dilute Caelyx in 250mL of 5% (50 mg/mL) glucose solution for infusion.** ❖**For doses ≥ 90mg: dilute Caelyx in 500mL of 5% (50 mg/mL) glucose solution for infusion.** ❖**The intravenous catheter and tubing should be flushed with 5% glucose solution for infusion between administration of the 2 medicinal products. Day 4 dosing of both medicinal product may be delayed up to 48 hours as medically necessary. Doses of bortezomib should be at least 72 hours apart. The first infusion of Caelyx should be administered over 90 minutes, as follows:** • **10mL over first 10 minutes** • **20mL over next 10 minutes** • **40mL over next 10 minutes** • **then, complete the infusion over a total of 90 minutes.** ❖**Subsequent doses of Caelyx will be administered over 1 hour, as tolerated. If an infusion reaction to Caelyx occurs, stop the infusion and after the symptoms resolve, attempt to administer the remaining Caelyx over 90 minutes, as follows:** • **10 ml over first 10 minutes** • **20 ml over next 10 minutes** • **40 ml over next 10 minutes** • **then, complete the remaining infusion over a total of 90 minutes.** ❖**Infusion may be given through a peripheral vein or a central line.**	SCHERING-PLOUGH SDN BHD LEVEL 12, WISMA UOA DAMANSARA II NO. 6, JALAN CHANGKAT SEMANTAN, DAMANSARA HEIGHTS 50490 KUALA LUMPUR

❖**For multiple myeloma patients treated with Caelyx in combination with bortezomib who experience PPE or stomatitis, the Caelyx dose should be modified as described in Table 3 and 4 below respectively. For more detailed information on bortezomib dosing and dosage adjustments, see the Prescribing Information for bortezomib.**

Table 2. DOSAGE ADJUSTMENTS FOR CAELYX + BORTEZOMIB COMBINATION THERAPY - PATIENTS WITH MULTIPLE MYELOMA

Patient Status	Caelyx	Bortezomib
Fever $\geq$ 38°C and ANC < 1,000/mm^3	Do not dose this cycle if before Day 4; if after Day 4, reduce next dose by 25 %.	Reduce next dose by 25 %
On any day of medicine administration after Day 1 of each cycle: Platelet count < 25,000/mm^3 Hemoglobin < 8g/dl ANC < 500/mm^3	Do not dose this cycle if before Day 4; if after Day 4 reduce next dose by 25 % in the following cycles if bortezomib is reduced for hematologic toxicity.*	Do not dose; if 2 or more doses are not given in a cycle, reduce dose by 25 % in following cycles.
Grade 3 or 4 non-hematologic medicine related toxicity	Do not dose until recovered to Grade < 2 and reduce dose by 25 % for all subsequent doses.	Do not dose until recovered to Grade < 2 and reduce dose by 25 % for all subsequent doses.
Neuropathic pain or peripheral neuropathy	No dosage adjustments.	See the Prescribing Information for bortezomib

***for more information on bortezomib dosing and dosage adjustment, see the Prescribing Information for bortezomib**

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
4.	4.1	**Inj Vincristine Sulphate 1mg in 1mL** (1mg/mL Vincristine Sulphate)	❖**Vincristine may be useful in patients with true idiopathic thrombocytopenic purpura resistant to the usual treatment, but is not recommended as primary treatment for this disorder.** **Posology :** ❖ **This preparation is for intravenous use only and is usually administered at weekly intervals. Vincristine should not be given intramuscularly, subcutaneously or intrathecally. Intrathecal use of vincristine usually results in death. When dispensed, syringes and vials containing this product should be labeled: FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY ANY OTHER ROUTE.** ❖ **Vincristine Sulphate Injection may be injected into the tubing or sidearm of a free flowing I.V. infusion of 0.9% sodium chloride or 5% glucose, or directly into a vein over about one minute. Care should be taken to avoid extravasation. Vincristine Sulfate Injection should not be diluted in solutions that raise or lower the pH outside the range of 3.5 to 5.5. It should not be mixed with anything other than 0.9% sodium chloride or 5% glucose.** ❖ **Always check the needle position before injecting vincristine. If there is a swelling or other evidence of injection site leakage cease the injection/infusion and give the remaining dose at another site. Immediately apply local measures (hyaluronidase, local heat) to try to reduce both discomfort and the risk of cellulitis.** ❖ **Vincristine has been given by many different dosing schemes and in combination with many other drugs.**	PFIZER (MALAYSIA) SDN. BHD. LEVEL 3&4, BANGUNAN PALM GROVE NO. 14, JALAN GLENMARIE (PERSIARAN KERJAYA), SECTION U1 40150 SHAH ALAM, SELANGOR
	4.2	**Inj Vincristine Sulphate 2mg in 2mL** (2mg/mL Vincristine Sulphate)		

			As the range between therapeutic and toxic levels is narrow and the response is varied, the dosage must always be carefully adjusted according to the needs of the individual. **Children:** **The usual dose is 1.5-2.0mg/m^2 body surface area.** **For children <10kg or body surface area <1m^2** **0.05mg/kg weekly.** **Adults:** **The usual dose is 0.4-1.4mg/m^2 body surface area.** ❖ **Conditions requiring dosage adjustment: Patients with biliary obstruction; pre-existing neuropathies; liver dysfunction or jaundice; and the elderly.** ❖ **A direct serum bilirudin >3mg/100mL should prompt a 50% reduction in dosage.** ❖ **When used in combination with L-asparaginase, vincristine sulphate should be given 12 to 24 hours before the administration of the enzyme in order to minimise toxicity (see Interactions with other drugs {in the package insert}); administering L-asparaginase before vincristine may reduce hepatic clearance of vincristine sulphate.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
5.	5.1 5.2	**Taxotere 20mg/ 0.5mL Vial** (20mg Docetaxel trihydrate) **Taxotere 80mg/ 2mL Vial** (80mg Docetaxel trihydrate)	❖**TAXOTERE in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.** **Posology:** ❖**<u>Head and neck cancer</u>** **Patients must receive premedication with antiemetics and appropriate hydration (prior to and after cisplatin administration). Prophylactic G-CSF may be used to mitigate the risk of hematological toxicities. All patients on the docetaxel-containing arm of the TAX 323 and TAX 324 studies, received prophylactic antibiotics.** ❖**Induction chemotherapy followed by radiotherapy (TAX 323)** **For the induction treatment of inoperable locally advanced squamous cell carcinoma of the head neck (SCCHN), the recommended dose of TAXOTERE is 75 mg/m^2 as a 1 hour infusion followed by cisplatin 75 mg/m^2 over 1 hour, on day one, followed by 5-fluorouracil as a continuous infusion at 750 mg/m^2 per day for five days. This regimen is administered every 3 weeks for 4 cycles. Following chemotherapy, patients should receive radiotherapy.** ❖**Induction chemotherapy followed by chemoradiotherapy (TAX 324)** **For the induction treatment of patients with locally advanced (technically unresectable, low probability of surgical cure, and aiming at organ preservation) squamous cell carcinoma of the head and neck (SCCHN), the recommended dose of docetaxel is 75 mg/m^2 as a 1 hour intravenous infusion on day 1, followed by cisplatin 100 mg/m^2 administered as a 30 min to 3 hour infusion, followed by 5-fluorouracil 1000**	SANOFI-AVENTIS (MALAYSIA) SDN. BHD. 8TH FLOOR, PNB DAMANSARA NO. 19, LORONG DUNGUN DAMANSARA HEIGHTS 50490 KUALA LUMPUR WILAYAH PERSEKUTUAN

			mg/m^2 as a continuous infusion from day 1 to day 4. This regimen is administered every 3 weeks for 3 cycles. Following chemotherapy, patients should receive chemoradiotherapy. **For cisplatin and 5-fluorouracil dose modifications, see the corresponding summary of product characteristics.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
6.	6.1	**Seroquel XR Extended Release Tablet 50mg** (57.56mg Quetiapine Fumarate (equivalent to 50mg quetiapine free base))	❖**Seroquel XR is effective in preventing relapse in stable schizophrenic patients who have been maintained on Seroquel XR.** ❖**Seroquel XR is indicated for the treatment of moderate to severe manic episodes in the framework of bipolar disorder.** ❖**Seroquel XR is indicated for the treatment of major depressive episodes in bipolar disorder.** ❖**Seroquel XR is not indicated for the prevention of recurrence of manic or depressive episodes.** **Posology:** ❖**Seroquel XR should be administered once daily, without food. The tablets should be swallowed whole and not split, chewed or crushed.** ❖**Adults:** **For the treatment of schizophrenia and moderate to severe manic episodes associated with bipolar disorder.** ❖**Seroquel XR should be administered at least one hour before a meal. The daily dose at the start of therapy is 300 mg on Day 1 and 600 mg on Day 2. The recommended daily dose is 600 mg, however if clinically justified the dose may be increased to 800 mg daily. The dose should be adjusted within the effective dose range of 400 mg to 800 mg per day, depending on the clinical response and tolerability of the patient. For maintenance therapy in schizophrenia no dosage adjustment is necessary.** ❖**For the treatment of depressive episodes associated**	ASTRAZENECA SDN BHD WISMA PRISMA 17 JALAN SRI SEMANTAN SATU DAMANSARA HEIGHTS 50490 KUALA LUMPUR
	6.2	**Seroquel XR Extended Release Tablet 200mg** (230.26mg Quetiapine Fumarate (equivalent to 200mg quetiapine free base))		
	6.3	**Seroquel XR Extended Release Tablet 300mg** (345.38mg Quetiapine Fumarate (equivalent to 300mg quetiapine free base))		
	6.4	**Seroquel XR Extended Release Tablet 400mg** (460.50mg Quetiapine Fumarate (equivalent to 400mg quetiapine free base))		

			with bipolar disorder ❖ **Seroquel XR should be administered at bedtime. The daily dose for the first four days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). The recommended daily dose is 300 mg. Depending on the patient's response Seroquel XR maybe titrated up to 600 mg daily. Antidepressant efficacy was demonstrated at 300 mg and 600 mg/day, however no additional benefit was seen in the 600 mg group above 300 mg daily during short-term treatment.** ❖ **When treating depressive episodes in bipolar disorder, treatment should be prescribed by physicians experienced in treating bipolar disorder.** ❖ **Switching from Seroquel immediate-release tablets:** ❖ **For more convenient dosing, patients who are currently being treated with divided doses of immediate release Seroquel tablets may be switched to Seroquel XR at the equivalent total daily dose taken once daily. Individual dosage adjustments may be necessary.** ❖ **Elderly:** **As with other antipsychotics, Seroquel XR should be used with caution in the elderly, especially during the initial dosing period. The rate of dose titration of Seroquel XR may be need to be slower, and the daily therapeutic dose lower, than that used in younger patients. The mean plasma clearance of quetiapine was reduced by 30% to 50% in elderly patients when compared to younger patients. Elderly patients should be started on 50 mg/day. The dose can be increased in increments of 50 mg/day to an effective dose, depending on the clinical response and tolerability of the individual patient.**	

			❖**Efficacy and safety has not been evaluated in patients over 65 years with depressive episodes in the framework of bipolar disorder.** ❖**Children and Adolescents:** **The safety and efficacy of Seroquel XR have not been evaluated in children and adolescents.** ❖**Renal impairment:** **Dosage adjustment is not necessary in patients with renal impairment.** ❖**Hepatic impairment:** **Quetiapine is extensively metabolized by the liver. Therefore, Seroquel XR should be used with caution in patients with known hepatic impairment, especially during the initial dosing period. Patients with hepatic impairment should be started on 50 mg/day. The dose can be increased in increments of 50 mg/day to an effective dose, depending on the clinical response and tolerability of the individual patient.**	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
7.	7.1	**GARDASIL SUSPENSION FOR INJECTION** Each 0.5mL dose contains: HPV type 6 L1 protein 20mcg HPV type 11 L1 protein 40mcg HPV type 16 L1 protein 40mcg HPV type 18 L1 protein 20mcg	❖**Vulvar and vaginal cancer caused by HPV types 16 and 18.**	MERCK SHARP & DOHME (I.A.) CORP. MALAYSIA BRANCH T2-9, JAYA 33, NO. 3 (LOT 33), JALAN SEMANGAT, SEKSYEN 13, 46100 PETALING JAYA, SELANGOR

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Year 2009

Products Approved For Additional Indication (DCA 216 – 21 Mei 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**ARCOXIA 90MG TABLET** (90mg Etoricoxib)	❖**Treatment of ankylosing spondylitis (AS).** **Posology:** ❖**The recommended dose is 90mg once daily.** ❖**The dose for ankylosing spondylitis should not exceed 90 mg daily.**	MERCK SHARP & DOHME (I.A.) CORP. MALAYSIA BRANCH T2-9, JAYA 33, NO. 3 (LOT 33) JALAN SEMANGAT, SEKSYEN 13 46100 PETALING JAYA SELANGOR.
2.	2.1	**HUMIRA SOLUTION FOR INJECTION** (Adalimumab 40mg/0.8mL)	❖**Psoriatic Arthritis** **Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti – rheumatic drugs.** ❖**Plaque Psoriasis** **Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.**	ABBOTT LABORATORIES (M) SDN BHD NO. 22, JALAN PEMAJU U1/15, SECTION U1 HICOM – GLENMARIE INDUSTRIAL PARK 40150 SHAH ALAM SELANGOR

Maklumat tambahan indikasi untuk upload pada laman web

Year 2009

Products Approved For Additional Indication (DCA 217 – 25 Jun 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**AVASTIN INJECTION 25MG/ML** (Bevacizumab 25mg/ml)	❖ **Metastatic Colorectal Cancer (mCRC)** ❖ **Avastin (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.**	**ROCHE (M) SDN BHD, 14TH FLOOR, WEST BLOCK, WISMA SELANGOR DREDGING 142 JALAN AMPANG 50450 KUALA LUMPUR**
2.	2.1 2.2	**XELODA TABLET 150MG** (150mg Capecitabine) **XELODA TABLET 500MG** (500mg Capecitabine)	❖ **Xeloda is indicated for the treatment of patients with metastatic colorectal carcinoma.**	**ROCHE (MALAYSIA) SDN BHD, WISMA SELANGOR DREDGING, 142, JALAN AMPANG, 50450 KUALA LUMPUR, MALAYSIA.**
3.	3.1 3.2	**CANCIDAS INJECTION 50 MG/VIAL** (54.6mg Caspofungin Acetate) **CANCIDAS INJECTION 70 MG/VIAL** (75.6mg Caspofungin Acetate)	❖ **CANCIDAS is indicated in pediatric patients (12 months and older) for:** ❖ **Empirical treatment for presumed fungal infections in febrile, neutropenic patients.** ❖ **Treatment of Invasive Candidiasis, including candidemia.** ❖ **Treatment of Esophageal Candidiasis** ❖ **Treatment of Invasive aspergillosis in patients who are refractory to or intolerant of other therapies (i.e. amphotericin B, lipid formulations of amphotericin B, and/or itraconazole).** ❖ **CANCIDAS has not been studied as initial therapy for invasive aspergillosis.**	**MERCK SHARP & DOHME (I.A.) CORP. MALAYSIA BRANCH T2-9, JAYA 33, NO. 3 (LOT 33) JALAN SEMANGAT, SEKSYEN 13 46100 PETALING JAYA SELANGOR**

4	4.1 4.2 4.3	**CRESTOR 5MG TABLET** (5.2mg rosuvastatin calcium equivalent to 5mg rosuvastatin) **CRESTOR 10MG TABLET** (10.4mg rosuvastatin calcium equivalent to 10mg rosuvastatin) **CRESTOR 20MG TABLET** (20.8mg rosuvastatin calcium equivalent to 20mg rosuvastatin)	❖ **Crestor is indicated as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).**	**ASTRAZENECA SDN BHD** **WISMA PRIMA 17** **JALAN SRI SEMANTAN SATU** **DAMANSARA HEIGHT** **50490 KUALA LUMPUR**

Products Approved For Additional Indication (DCA 218 – 30 JULAI 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2 1.3	**KOGENATE®- FS 250 IU INJECTION** (Octocog alfa 250 IU/vial) **KOGENATE®- FS 500 IU INJECTION** (Octocog alfa 500 IU/vial) **KOGENATE®- FS 1000 IU INJECTION** (Octocog alfa 1000 IU/vial)	❖ **Routine Prophylaxis in children with Hemophilia A with No Pre-existing Joint Damage)** ❖ **Kogenate® FS is indicated for routine prophylactic treatment to reduce the frequency of bleeding episodes and the risk of joint damage in children with no pre-existing joint damage.**	**BAYER CO. (MALAYSIA) SDN. BHD. T1-14 JAYA 33, NO.3, JALAN SEMANGAT, SEKSYEN 13, 46200 PETALING JAYA, SELANGOR**
2.	2.1	**GADOVIST 1.0 MMOL/ML SOLUTION FOR INJECTION** (604.72mg/ml of gadobutrol equivalent to 1.0mmol gadobutrol containing 157.25mg gadolinium)	❖ **Gadovist is indicated for contrast enhancement in Magnetic Resonance Angiography (CE-MRA).** **Posology:** **General Information** ❖ **The dose required is administered intravenously as a bolus injection. Contrast-enhanced MRI can commence immediately afterwards (shortly after the injection depending on the pulse sequences used and the protocol for the examination). Optimal opacification is observed within a period of about 15 minutes after injection of Gadovist for other indications (time depending on type of**	**BAYER CO. (MALAYSIA) SDN. BHD. T1-14 JAYA 33, NO.3, JALAN SEMANGAT, SEKSYEN 13, 46200 PETALING JAYA, SELANGOR**

			lesion/tissue). Enhancement generally lasts up to 45 minutes after injection of Gadovist. ❖ **General safety rules customary for magnetic resonance imaging must be observed.** ❖ **T_1-weighted scanning sequences are particularly suitable for contrast-enhanced examinations.** ❖ **For brain perfusion studies, T_2*-weighted sequences are recommended.** ❖ **Intravascular administration of contrast media should, if possible, be done with the patient lying down. After the administration, the patient should be kept under observation for at least 30 minutes, since experience with contrast media shows that the majority of all undesirable effects occur within this time.** **Dosage:** ❖ **<u>CNS indications</u>:** • **The recommended dose for adults is 0.1mmol per kilogram body weight (mmol/kg BW). This is equivalent to 0.1mL/kg BW of the 1.0M solution or 0.2mL/kg of the 0.5M solution.** ❖ **If a strong clinical suspicion of a lesion persists despite an unremarkable MRI or when more accurate information might influence management or therapy of the patient, a further injection of up to 0.2mL/kg body weight within 30 minutes of the first injection may be performed. The dose must not exceed 0.1mmol Gadovist / kg body weight in patients with impaired renal function.**	

			❖ **<u>CE-MRI of liver and kidneys</u>:** • **The recommended dose for adults is 0.1mmol per kilogram body weight (mmol/kg BW). This is equivalent to 0.1mL/kg BW of 1.0M solution.** **CE-MRA** **Imaging of 1 field of view: (FOV)** — **7.5 ml for body weight below 75 kg, 10 ml for body weight of 75 kg and higher (corresponding to 0.1-0.15 mmol/kg BW)** **Imaging of >1 field of view: (FOV)** — **15 ml for body weight below 75 kg, 20 ml for body weight of 75 kg and higher (corresponding to 0.2-0.3 mmol/kg BW)** ❖ **<u>Use in children</u>** • **Specific data on the use of gadobutrol in patients younger than 18 years are not available. In these patients the product should only be used after the physicians careful consideration of the benefit against the potential risk.**	
3	3.1 3.2 3.3	**CRESTOR 5MG TABLET** (5.2mg rosuvastatin calcium equivalent to 5mg rosuvastatin) **CRESTOR 10MG TABLET** (10.4mg rosuvastatin calcium equivalent to 10mg rosuvastatin) **CRESTOR 20MG**	❖ **Prevention of Cardiovascular Events. In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease, CRESTOR is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina, or arterial revascularization).**	**ASTRAZENECA SDN BHD** **WISMA PRIMA 17** **JALAN SRI SEMANTAN SATU** **DAMANSARA HEIGHT** **50490 KUALA LUMPUR**

		TABLET (20.8mg rosuvastatin calcium equivalent to 20mg rosuvastatin)		

Products Approved For Additional Indication (DCA 219 – 27 OGOS 2009)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	**AERIUS TABLET** (5mg Desloratadine) **AERIUS SYRUP 0.5 MG/ ML** (0.5mg/ml Desloratadine)	❖ Aerius Syrup 0.5mg/mL - AERIUS Syrup is also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives. ❖ Aerius Tablet - AERIUS Tablets are also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives. Posology ❖ Aerius Syrup 0.5mg/mL - The prescriber should be aware that most cases of rhinitis below 2 years of age are of infections origin and there are no data supporting the treatment of infectious rhinitis with AERIUS. - Children 6 through 11 years of age: 5 ml (2.5 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria.	**SCHERING-PLOUGH SDN BHD** **LEVEL 12, WISMA UOA DAMANSARA II** **NO. 6, JALAN CHANGKAT SEMANTAN** **DAMANSARA HEIGHTS** **50490 KUALA LUMPUR** **WILAYAH PERSEKUTUAN**

			- Children 1 through 5 years of age: 2.5 ml (1.25 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria. - In adults and adolescents (12 years of age and over): 10 ml (5 mg) AERIUS Syrup once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria. - Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during allergen exposure periods. ❖ <u>Aerius Tablet</u> - Adults and Adolescents (12 years of age and older): One AERIUS 5 mg film-coated tablet	

			once a day regardless of mealtime for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria. For oral use. - Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during allergen exposure periods.	
2.	2.1 2.2 2.3 2.4	**GLIVEC 50MG CAPSULES** (59.75.5mg Imatinib mesylate corresponding to 50mg of Imatinib free base) **GLIVEC 100MG CAPSULES** (119.5mg Imatinib mesylate corresponding to 100mg of Imatinib free base) **GLIVEC 100MG TABLETS** (119.5mg Imatinib mesylate corresponding to 100mg of Imatinib free base) **GLIVEC 400MG TABLETS** (478mg Imatinib mesylate corresponding to 400mg of Imatinib free base)	❖ <u>Glivec is indicated for the treatment of</u> - adjuvant treatment of adult patients following resection of GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. - The effectiveness of Glivec is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and SM and on objective response rates in GIST and DFSP and on recurrence-free survival in adjuvant GIST. The experience with Glivec in patients with MDS/MPD	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** **LEVEL 15, CREST, 3 TWO SQUARE** **NO.2, JALAN 19/1,** **46300 PETALING JAYA,** **SELANGOR**

			associated with PDGFR gene re-arrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival in these diseases. Posology ❖ Dosage in GIST - The recommended dose of Glivec is 400mg/day for patients with unresectable and/or metastatic, malignant GIST. A dose increase from 400mg to 600mg or 800mg for patients may be considered in the absence of adverse drug reactions if assessments demonstrate an insufficient response to therapy. Treatment with Glivec in GIST patients should be continued until disease progression. - The recommended dose of Glivec is 400mg/day for the adjuvant treatment of adult patients following resection of GIST. In the adjuvant setting the optimal treatment duration with Glivec is not known. Length of treatment in the clinical trial supporting this indication was 12 months.	
3	3.1 3.2	**NEXIUM IV 40 MG** (40mg Esomeprazole sodium) **NEXIUM 20 MG TABLET** (20mg Esomeprazole as 22.3mg magnesium trihydrate) **NEXIUM 40 MG TABLET**	❖ Nexium IV 40mg Nexium for injection and infusion is indicated for: • Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers. ❖ Nexium 20mg & 40mg tablets	**ASTRAZENECA SDN. BHD.** **GROUND FLOOR, WISMA PRIMA** **17, JALAN SEMANTAN SATU** **50490 KUALA LUMPUR** **WILAYAH PERSEKUTUAN**

	3.3	(40mg Esomeprazole as 44.5mg magnesium trihydrate)	Nexium tablets are indicated for: • Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers. Posology ❖ Nexium IV 40mg Prevention of rebleeding of gastric and duodenal ulcers • Following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers, 80 mg should be administered as a bolus infusion over 30 minutes, followed by a continuous intravenous infusion of 8mg/h given over 3 days (72 hours). • The parenteral treatment period should be followed by oral acid suppression therapy. Method of administration • 80mg bolus dose - The reconstituted solution should be given as a continuous intravenous infusion over 30 minutes. • 8mg/h dose - The reconstituted solution should be given as a continuous intravenous infusion over a period of 71.5 hours (calculated rate of infusion of 8mg/h. See “Shelf Life” for shelf-life of the reconstituted solution.) ❖ Nexium 20mg & 40mg tablets Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.	

			40mg once daily for 4 weeks after i.v. induced prevention of rebleeding of peptic ulcers.	

Initiation of Intensive Care Unit Sedation	For adult patients**: a loading infusion of one mcg/kg over 10 minutes.** For patients over 65 years of age**: a dose reduction should be considered.** For patients with impaired hepatic or renal function**: a dose reduction should be considered.**
Maintenance of Intensive Care Unit Sedation	For adult patients**: a maintenance infusion of 0.2 to 0.7mcg/kg/hr. The rate of the maintenance infusion should be adjusted to achieve the desired level of sedation.** For patients over 65 years of age: **a dose reduction should be considered.** For patients with impaired hepatic or renal function**: a dose reduction should be considered.**
Initiation of Procedural Sedation:	For adult patients**: a loading infusion of one mcg/kg over 10 minutes. For less invasive procedures such as ophthalmic surgery, a loading infusion of 0.5mcg/kg given over 10 minutes may be suitable.** For awake fiberoptic intubation patients**: a loading infusion of one mcg/kg over 10 minutes.** For patients over 65 years of age**: a loading infusion of 0.5mcg/kg over 10 minutes.** For patients with impaired hepatic or renal function**: a dose reduction should be considered.**
Maintenance of Procedural Sedation:	For adult patients**: the maintenance infusion is generally initiated at 0.6mcg/kg/hr and titrated to achieve desired clinical effect with doses ranging from 0.2 to 1mcg/kg/hr. The rate of the maintenance infusion should be adjusted to achieve the targeted level of sedation.** For awake fiberoptic intubation patients**: a maintenance infusion of 0.7mcg/kg/hr is recommended until the endotracheal tube is secured.** For patients over 65 years of age: **a dose reduction should be considered.** For patients with impaired hepatic or renal function**: a dose reduction should be considered.**

2.	2.1 2.2	**MULTIHANCE INJECTION SOLUTION** (Gadobenate Dimeglumine 529mg/ml equivalent to gadobenic acid 334mg/ml) **MULTIHANCE INJECTION SOLUTION** (Gadobenate Dimeglumine 529mg/ml equivalent to gadobenic acid 334mg/ml)	❖ *MultiHance is a paramagnetic contrast agent for use in diagnostic magnetic resonance imaging (MRI) indicated for:* - *Contrast-enhanced MR-angiography where it improves the diagnostic accuracy for detecting clinically significant steno-occlusive vascular disease in patients with suspected or known vascular disease of the abdominal or peripheral arteries.* *<u>Posology</u>* ❖ *MRI of the liver: the recommended dose of MultiHance injection in adult patients is 0.05 mmol/kg body weight. This corresponds to 0.1 mL/kg of the 0.5 m solution.* ❖ *MRI of the brain and spine: the recommended dose of MultiHance injection in adult patients is 0.1 mmol/kg body weight. This corresponds to 0.2 mL/kg of the 0.5 M solution.* ❖ *<u>MRA: the recommended dose of MultiHance injection in adult patients is 0.1 mmol/kg body weight. This corresponds to 0.2 mL/kg of the 0.5 M solution</u>.* ❖ *MultiHance should be drawn up into the syringe immediately before use and should not be diluted. Any unused product should be discarded and not be used for other MRI examinations.* ❖ *To minimize the potential risks of soft tissue extravasation of MultiHance, it is important to ensure that the i.v. needle or cannula is correctly inserted into a vein.* ❖ *Liver and Brain and Spine: the product should be administered intravenously either as a bolus or slow injection (10 mL/min.).* ❖ *<u>MRA: the product should be administered intravenously as a bolus injection, either manually or using an automatic injector system.</u>* ❖ *The injection should be followed by a saline flush.*	**IDS SERVICES (MALAYSIA) SDN BHD** **LOT 6, PERSIARAN PERUSAHAAN** **SEC 23, KAWASAN PERUSAHAAN SHAH ALAM** **40300 SHAH ALAM** **SELANGOR**

			Post-contrast imaging acquisition: *Liver* — *Dynamic imaging:* — *Immediately following bolus injection.* *Liver* — *Delayed imaging:* — *Between 40 and 120 minutes following the injection, depending on the individual imaging needs.* *Brain and Spine* — *Up to 60 minutes after the administration.* *MRA* — *Immediately after the administration, with scan delay calculated on the basis of test bolus or automatic bolus detection technique.* *If an automatic contrast detection pulse sequence is not used for bolus timing, then a test bolus injection ≤2 mL of the agent should not be used to calculate the appropriate scan delay.* ❖ *The safety and efficacy of MultiHance have not been established in patients under 18 years old. Therefore, use of MultiHance in this patient group cannot be recommended.*	
3	3.1	**ACLASTA SOLUTION FOR INFUSION** **5 MG/100 ML** (5mg zoledronic acid (anhydrous), corresponding to 5.330mg zoledronic acid monohydrate per 100 ml)	❖ *Treatment and prevention of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in men at increased risk of fracture.* *Posology* ❖ *For the treatment of postmenopausal osteoporosis and osteoporosis in men, the recommended dose is a single intravenous infusion of 5 mg infusion of Aclasta administered once a year.* ❖ ❖ *For the treatment and prevention of glucocorticoid-induced osteoporosis in women and men, the recommended dose is a single intravenous infusion of 5*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** **LEVEL 15, CREST, 3 TWO SQUARE NO.2, JALAN 19/1, 46300 PETALING JAYA, SELANGOR WILAYAH PERSEKUTUAN**

			mg infusion of Aclasta administered once a year. ❖ ❖ *In patients with a recent low-trauma hip fracture, it is recommended to give the Aclasta infusion two or more weeks after hip fracture repair.* ❖ ❖ *For the treatment of Paget's disease the recommended dose is a single intravenous infusion of 5 mg Aclasta.* ❖ ❖ *Retreatment of Paget's disease: Specific retreatment data are not available. After a single treatment with Aclasta in Paget's disease, an extended remission period is observed in responding patients.* ❖ *Aclasta (5 mg in 100 mL ready to infuse solution) is administered intravenously via a vented infusion line, given at a constant infusion rate. The infusion time must not be less than 15 minutes.* ❖ ❖ *Patients must be appropriately hydrated prior to administration of Aclasta. This is especially important for patients receiving diuretic therapy.* ❖ ❖ *Adequate calcium and vitamin D intake is important in patients with osteoporosis if dietary intake is inadequate.* ❖ ❖ *Elevated bone turnover is a characteristic of Paget's disease of bone. It is strongly advised that patients with Paget's disease receive the recommended daily allowance of supplemental calcium and vitamin D and this should be ensured during the initial 10 days following Aclasta administration.* ❖ ❖ *The incidence of post-dose symptoms occurring within the first three days after administration of Aclasta can be reduced with the administration of paracetamol or ibuprofen shortly following Aclasta administration.* ❖ ❖ *Patients with renal impairment* ❖ *The use of Aclasta in patients with creatinine clearance < 30 mL/min is not recommended due to lack of adequate clinical experience in this population.* ❖ ❖ *No dose adjustment is necessary in patients with creatinine clearance ≥ 30 mL/min.* ❖ ❖ *Patients with hepatic impairment*	

			❖ *No dose adjustment is required.* ❖ *Elderly (≥ 65 years)* ❖ *No dose adjustment is necessary since bioavailability, distribution and elimination were similar in elderly patients and younger subjects.* ❖ ❖ *Children and adolescents* ❖ *Aclasta has not been tested in children and adolescents and therefore should not be used in these age groups.*	
4	4.1 4.2 4.3 4.4	**APIDRA SOLOSTAR 100 UNITS/ML, SOLUTION FOR INJECTION IN A PRE-FILLED PEN** (Insulin glulisine 100u/ml) **APIDRA 100 U/ML- SOLUTION FOR INJECTION IN VIAL** (Insulin glulisine 100u/ml) **APIDRA 100 U/ML, 3ML CARTRIDGES FOR OPTIPEN- SOLUTION FOR INJECTION IN CARTRIDGE** (Insulin glulisine 100u/ml) **APIDRA 100 U/ML OPTISET- SOLUTION FOR INJECTION IN PRE-FILLED PEN** (Insulin glulisine 100u/ml)	❖ Treatment for adolescents and children 6 years or older with diabetes mellitus.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** **8TH FLOOR, PNB DAMANSARA** **NO. 19, LORONG DUNGUN** **DAMANSARA HEIGHTS** **50490 KUALA LUMPUR**

5	5.1 5.2	**NEUPOGEN PRE-FILLED SYRINGES 30MU/0.5ML** **NEUPOGEN 30 MIO U 0.3MG/ML VIAL**	❖ Neupogen® is indicated for the treatment of persistent neutropenia (ANC ≤ 1.0 X 10^9/l) in patients with advanced HIV infection, in order to reduce risk of bacterial infections, when other options to manage neutropenia are inappropriate.	**ROCHE (M) SDN. BHD.** **14th. FLOOR, WEST BLOCK** **WISMA SELANGOR DREDGING,** **142, JALAN AMPANG** **50450 KUALA LUMPUR** **WILAYAH PERSEKUTUAN**

- *Do not stop treatment abruptly or change the recommended dose without talking to your doctor first since this might lead to a transitory worsening of heart condition. Especially in patients with ischaemic heart disease, treatment must not be discontinued suddenly. If discontinuation is necessary, the daily dose is gradually decreased.*

❖ *Special populations*

➢ *<u>Renal or hepatic impairment:</u>*

- *Treatment of stable chronic heart failure: There is no information regarding pharmacokinetics of bisoprolol in patients with chronic heart failure and concomitant hepatic or renal impairment. Titration of the dose in these populations must therefore be made with particular caution.*

➢ *<u>Elderly:</u>*

- *No dosage adjustment is required.*

➢ *<u>Children</u>*

- *There is no paediatric experience with bisoprolol, therefore its use cannot be recommended for children.*

➢ *<u>Administration</u>*

- *Concor tablets are taken in the morning with or without food. They are swallowed with some liquid and not to be chewed.*

❖ *<u>Concor 2.5mg Tablet</u>*

➢ *Treatment of stable chronic heart failure*

1st week	*:*	*1.25mg bisoprolol hemifumarate (1/2 tablet Concor 2.5mg) once daily*
2nd week	*:*	*2.5mg bisoprolol hemifumarate (1 tablet Concor 2.5mg) once daily*
3rd week	*:*	*3.75mg bisoprolol hemifumarate (1 ½ tablets Concor 2.5mg) once daily*
4th – 7th week	*:*	*5mg bisoprolol hemifumarate (2 tablet Concor 2.5mg) once daily**
8th – 11th week	*:*	*7.5mg bisoprolol hemifumarate (3 tablet Concor 2.5mg) once daily**
12th week and beyond	*:*	*10mg bisoprolol hemifumarate (4 tablets Concor 2.5mg) once daily as maintenance treatment**

** Concor 2.5 mg is suitable for initial treatment of stable chronic heart failure. Higher strengths are available for maintenance treatment.*

❖ *<u>Concor 5 and 10 Film-Coated Tablet</u>*

➢ *Treatment of hypertension or angina pectoris*

- *In all cases the dose regimen is adjusted individually by your doctor, in particular according to the pulse rate and therapeutic success.*
- *The usual initial dose is 5mg bisoprolol hemifumarate (1/2 tablet of Concor 10mg or 1 tablet of Concor 5mg) once daily. If necessary, the dose may be increased to 10mg bisoprolol hemifumarate (1 tablet of Concor 10mg or 2 tablets of Concor 5mg) once daily.*

- *The maximum recommended dose is 20mg bisoprolol hemifumarate once daily.*

- *Concor must be used with caution in patients with hypertension or angina pectoris and accompanying heart failure.*

➢ *Treatment of stable chronic heart failure*

1st week	*:*	*1.25mg bisoprolol hemifumarate once daily**
2nd week	*:*	*2.5mg bisoprolol hemifumarate (1/2 tablet Concor 5mg) once daily**
3rd week	*:*	*3.75mg bisoprolol hemifumarate once daily**
4th – 7th week	*:*	*5mg bisoprolol hemifumarate (1/2 tablet Concor 10mg or 1 tablet Concor 5mg) once daily*
8th – 11th week	*:*	*7.5mg bisoprolol hemifumarate (1 ½ tablets Concor 5mg) once daily**
12th week and beyond	*:*	*10mg bisoprolol hemifumarate (1 tablet Concor 10mg or 2 tablets Concor 5mg) once daily as maintenance treatment*

**Concor 10mg / 5mg is not suitable for initial treatment of stable chronic heart failure. Lower strengths are available for this purpose.*

❖ *Special populations*

➢ *<u>Renal or hepatic impairment:</u>*

- *Treatment of hypertension or angina pectoris: In patients with liver or kidney function disorders of mild to moderate severity no dosage adjustment is normally required. In patients with severe renal impairment (creatinine clearance <20 ml/min) and in patients with severe hepatic impairment a daily dose of 10mg bisoprolol hemifumarate must not be exceeded.*