Year 2001

DCA 131 (28/12/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Topamax Tablet 25 mg 1.2 Topamax Tablet 50 mg 1.3 Topamax Tablet 100 mg 1.4 Topamax Tablet 200 mg (Topiramate)	• Seizures associated with Lennox-Gastaut Syndrome • Tonic clonic seizures	Johnson & Johnson S/B, Sel.
2.	1.1 Caelyx Concentrate For Infusion 2 mg/ml (Doxorubicin Liposome)	Caelyx is indicated for the treatment of advanced ovarian cancer in women who have failed a first-line platinum based chemotherapy regimen.	Schering-Plough S/B, Sel.

DCA 130 (29/11/2001)

Additional Indications Approved - Latest

- None -

DCA 129 (26/10/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Efexor XR 75 mg Capsule 1.2 Efexor XR 150 mg Capsule (Venlafaxine HCl)	• For the treatment of depression, including depression associated with anxiety, in hospitalised patient. • Treatment of anxiety, or Generalized Anxiety Disorder (GAD) including long term treatment. • The effectiveness of Efexor XR in long term use for GAD has been evaluated for up to 6 month in controlled clinical trials	Wyeth (M) S/B
2.	2.1 Efexor Tablet 37.5 mg Tablet 2.2 Efexor Tablet 50 mg Tablet	For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes	Wyeth (M) S/B

	2.3 Efexor Tablet 75 mg Tablet 2.4 Efexor Tablet XR 75 mg Capsule 2.5 Efexor Tablet XR 150 mg Capsule (Venlafaxine HCl)		
3.	1.1 Neurontin 300 mg Capsules 1.2 Neurontin 400 mg Capsules (Gabapentin)	Treatment of neuropathic pain which include pain, post-herpetic neuralgia and trigeminal neuralgia in adults.	Pfizer (M) S/B

DCA 128 (20/09/2001)

Additional Indications Approved - Latest

- Tiada -

DCA 127 (23/08/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Concor 5 Film Coated Tablet (Bisoprolol Fumarate)	Treatment of stable chronic moderate to severe heart failure with reduced systolic ventricular function (ejection fraction £ 35%, based on echocardiography) in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.	Zuellig Pharma S/B

DCA 126 (26/07/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Tritace Tablet 2.5 mg 1.2 Tritace Tablet 5.0 mg (Ramipril)	• For reducing the risk of myocardial infarction, stroke, cardiovascular death or the need for revascularisation procedures in patients 55 years or more who have clinical evidence of coronary artery disease, stroke or peripheral vascular disease • For reducing the risk of myocardial	Aventis Farma SA (M), Selangor

		infarction, stroke, cardiovascular death or revascularisation procedures in diabetic patients 55 years or more with one or more of the following risk factors : systolic blood pressure > 160 mgHg or diastolic blood pressure > 90 mmHg (or on antihypertensive treatment); total cholesterol > 5.2 mmol/L, HDL cholesterol < 0.9 mmol/L; current smoker; known microalbuminuria; any evidence of previous vascular disease.	
2.	2.1 Prevacid 30 mg Capsule (Lansoprazole)	Eradication of H. Pylori from upper gastrointestinal tract in-patients with peptic ulcer (duodenal or benign gastric ulcer) when used in combination with appropriate antibiotics.	Zuellig Pharma S/B
3.	3.1 Fosamax Tablet 5 mg 3.2 Fosamax Tablet 10 ng (Alendronate)	Indicated for treatment and prevention of Glucocorticoid induced osteoporosis in men and women.	Merck Sharp & Dohme, Selangor
4.	4.1 Xeloda Tablet 150 mg 4.2 Xeloda Tablet 500 mg (Capecitabine)	First-line treatment of patients with metastatic colorectal carcinoma	Roche (M) S/B

DCA 125 (28/06/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Cellcept Capsule 250 mg 1.2 Cellcept Capsule 500 mg (Mycophenolate mofetil)	Prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants.	Roche (Malaysia) S/B
2.	2.1 Humatrope 1.33 mg (4 iu) 2.1 Humatrope 5.33 mg (16 iu) {Somatropin	Paediatric Indications: Somatropin is also indicated for the treatment of growth retardation in prepubertal children with chronic renal insufficiency.	Eli Lilly (M) S/B

	(rDNA)}		

DCA 124 (07/06/2001)

Additional Indications Approved - Latest

- None -

DCA 123 (17/05/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1.1 Taxotere 80 mg/2 ml 1.2 Taxotere 20 mg/0.5 ml (Docetaxel)	Treatment in combination with doxorubicin of patients with locally advanced or metastatic breast cancer, who have not previously received cytotoxic therapy for this condition.	Aventis Farma SA (M) S/B
2.	2.1 Norvir Oral Solution 80 mg/ml(Ritonavir)	Norvir is Indicated in combination with nucleoside analogue for the treatment of HIV-infection in children aged 2 years and older and adults when therapy is warranted.	Abbott Labs (M) S/B

DCA 122 (24/04/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	Arimidex Tablet 1 mg (Anastrozole)	Treatment of advanced breast cancer in post-menopausal women. Efficacy has not been demonstrated in oestrogen receptor negative patients unless they had a previous positive clinical response to tamoxifen	Astra Pharmaceutical (M) S/B
2.	Persantin Injection 10 mg/2 ml (Diyprimadole USP)	As an alternative to exercise testing in myocardial perfusion thallium imaging for the evaluation of coronary artery disease, particularly in patients who cannot exercise adequately. The sensitivity and specifically of exercise thallium imaging and Persantin thallium imaging is almost identical	Boehringer Ingelheim (M) S/B

DCA 121 (27/02/2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder

1.	1.1 Videx Tablet 25 mg (Didanosine 25 mg) 1.2 Videx Tablet 50 mg (Didanosine 50 mg) 1.3 Videx Tablet 100 mg (Didanosine 100 mg) 1.4 Videx Paediatric Powder For Suspension 2 g (Didanosine 26 mg) 1.5 Videx Paediatric Powder For Suspension 4 g (Didanosine 46 mg)	For the treatment of HIV-infected patients in appropriate antiretroviral regimens, including use in combination with other nucleoside analogues, non-nucleoside reverse transcriptase inhibitors, and HIV protease inhibitors.	Brystol-Myers Squibb (M) S/B
2.	2.1 Lescol 20 mg capsule (Fluvastatin Sodium 21.06 mg equi. to 20 mg Fluvastatin) 2.2 Lescol 40 mg capsule (Fluvastatin Sodium 42.12 mg equi. to 40 mg Fluvastatin)	As an adjunct to diet for the treatment of elevated total-C, LDL-C, apo B and TG levels in patients with primary hypercholesterolaemia and primary mixed dyslipidaemia (Frederickson Types IIa and IIb), whose response to dietary restriction of saturated fat and cholesterol and other nonpharmacological measures has not been adequate.	Novartis Corporation (M) S/B
3.	Nasonex Aqueous Nasal Spray (Mometasone Furoate Monohydrate equi. to 50 Micrograms Mometasone Furoate)	NasonexTM Aqueous Nasal Spray is indicated for use in adults and children 3 years of age and older to treat symptoms of seasonal or perennial rhinitis. In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with NasonexTM is recommended two to four weeks prior to the anticipated start of the pollen season. Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. In a placebo-controlled clinical trial in which paediatric patients were administered NasonexTM 100 micrograms daily for one year, no reduction in growth velocity was	Schering-Plough S/B

		observed.	
3.	3.1 Humatrope 1.33 mg (4 IU) 3.2 Humatrope 5.33 mg (16 IU) (Somatropin) 3.3 Humatrope 5 mg (13 IU) (Somatropin)	Adult Patients Somatropin is indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency who meet both of the following two criteria: 1. *Adult Onset*: Patients who have growth hormone deficiency either alone, or with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or *Childhood Onset*: Patients who were growth hormone-deficient during childhood who have growth hormone deficiency confirmed as an adult before replacement therapy with Somatropin is started. and 2. Biochemical diagnosis of growth hormone deficiency, by means of a negative response to standard growth hormone stimulation test [maximum peak <5 ng/mL when measured by RIA (polyclonal antibody) or <2.5 ng/mL when measured by IRMA (monoclonal antibody)].	Eli Lilly (M) S/B
4.	4.1 Omniscan 0.5 mmol/ml (5 ml) (Gadodiamide 287 mg/ml) 4.2 Omniscan 0.5 mmol/ml (10 ml) (Gadodiamide 287 mg/ml) 4.3 Omniscan 0.5 mmol/ml (15 ml) (Gadodiamide 287 mg/ml) 4.4 Omniscan 0.5 mmol/ml (20 ml) (Gadodiamide 287 mg/ml)	Contrast medium for cranial and spinal magnetic resonance imaging (MRI) and for general MRI of the body thoracic (non cardiac), abdominal, pelvic and retroperitoneal after intravenous administration. The product provides contrast enhancement and facilities visualization of abnormal structures or lesions in various parts of the body including the CNS	Pharmaforte (M) S/B