

Year 2005

DCA 176 (15/12/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|------------|--|---|---|
| 1. | 1.1 | Flixonase Aqueous Nasal Spray (Fluticasone propionate) | In patients with allergic rhinitis, fluticasone propionate aqueous nasal spray is also indicated for the management of associated sinus pain and pressure. | GlaxoSmithKline Pharmaceutical Sdn. Bhd. 8th floor Menara Lien Hoe, 8 Persiaran Tropicana, 47410 Petaling Jaya |
| 2 | 2.1 2.2 | Glucophage 500mg tablet Glucophage 850mg tablet (Metformin hydrochloride) | Treatment of type 2 diabetes mellitus, when dietary management and exercise alone does not result in adequate glycaemic control. - In children from 10 years of age and adolescent, Glucophage 500mg or Glucophage 850mg film-coated tablet may be used as monotherapy or in combination with insulin. | Merck Sdn. Bhd. 4, Jalan U1/26, Seksyen U1, Hicom Glenmarie Industrial Park, Shah Alam |
| 3. | 3.1 | UFT Capsule (Tegafur & Uracil) | Folate plus Tegafur-Uracil combination therapy is indicated for colorectal cancer. | Luen Wah Medical Co. Sdn. Bhd. NO.43G & 43-1F, The Highway Centre, Jalan 51/205, 46050 Petaling Jaya |

DCA 175 (27/10/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-------------------|---|--|---|
| 1. | 1.1 1.2 1.3 | Avandia tablet 2mg Avandia tablet 4mg Avandia tablet 8mg (Rosiglitazone maleate) | Avandia is also indicated for use in combination with a sulphonylurea plus metformin (oral triple therapy) when diet, exercise, and both agents do not result in adequate glycaemic control. | GlaxoSmithKline Pharmaceutical Sdn. Bhd. 8th floor Menara Lien Hoe, 8 Persiaran Tropicana, 47410 Petaling Jaya |
| 2 | 2.1 | Nasonex Aqueous | Treatment of nasal polyps in patients 18 years of | Schering-Plough |

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| | Nasal Spray 0.05% (Mometasone Furoate Monohydrate Micronised) | age and older | Sdn. Bhd. Level 3-1, CP Tower, 11 Jalan 16/11, Pusat Dagang Seksyen 16, 46 350 Petaling Jaya, Selangor. |
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DCA 174 (29/9/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|-----|------------|--|--|--|
| 1. | 1.1 1.2 | Diovan 80mg film-coated tablet Diovan 160mg film-coated tablet (Valsartan) | Post-myocardial infarction Diovan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction. | Novartis Corporation (MALAYSIA) Sdn Bhd LOT 9, Jalan 26/1, Seksyen 26, Kawasan Perindustrian HICOM, 40400 Shah Alam, SELANGOR |
| 2 | 2.1 | Malarone tablet (Atovaquone & Proguanil HCL) | It is indicated for prophylaxis of Plasmodium falciparum malaria. The full indications will be as follows: Malarone is a fixed dose combination product which acts as a blood schizonticide and also has activity against hepatic forms of Plasmodium falciparum. It is indicated for :- - prophylaxis of Plasmodium falciparum malaria - treatment of Plasmodium falciparum malaria Because Malarone is effective against drug sensitive and drug resistant P. falciparum it is especially recommended for prophylaxis and treatment of P. falciparum malaria in areas where the pathogen may be resistant to other antimalarials. | GlaxoSmithKline Pharmaceutical Sdn. Bhd. 8th floor Menara Lien Hoe, 8 Persiaran Tropicana, 47410 Petaling Jaya |
| .3. | 3.1 | Mirena 20µg/24 hours intrauterine delivery system (Levonorgestrel) | Protection from endometrial hyperplasia during oestrogen replacement therapy. The full indications will be as follows: - Contraception. | Zuellig Pharma Sdn Bhd, Blok B, Level 3A, No 10 Jalan Bersatu 13/4, |

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| | | <ul style="list-style-type: none"> - Idiopathic menorrhagia. Mirena may be particularly useful in women with idiopathic menorrhagia requiring (reversible) contraception. - Protection from endometrial hyperplasia during oestrogen replacement therapy. | 46 200 Petaling Jaya, Selangor. |
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DCA 173 (1/9/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-------------------|--|--|---|
| 1. | 1.1 1.2 1.3 | Tritace 2.5mg tablet Tritace 5mg tablet Tritace 10mg tablet (Ramipril) | Prevention of progressive renal failure in patients with persistent proteinuria. | Aventis Farma SA (Malaysia) Sdn. Bhd. 8th. Floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights, 50490 KUALA LUMPUR |
| 2. | 2.1 2.2 2.3 | Taxol for Injection Concentrate, 30mg/5ml vial Taxol Injection 100mg/16.7ml vial Taxol Injection 300mg/50ml vial (Paclitaxel) | <p>Breast carcinoma</p> <p>The initial treatment of advanced or metastatic breast cancer in combination with trastuzumab in patients who over-express HER-2 at a 3+ level as determined by immunohistochemistry and for whom an anthracycline is not suitable.</p> <p>For Taxol Injection 300mg/50ml vial, it is also indicated for:</p> <p>Ovarian carcinoma</p> <ul style="list-style-type: none"> - First-line therapy in combination with a platinum compound for the treatment of advanced metastatic carcinoma of the ovary. - Second-line therapy for the treatment of advanced metastatic carcinoma of the ovary. <p>Non-small cell lung carcinoma</p> <ul style="list-style-type: none"> - First-line therapy in combination with a platinum compound or as a single agent for the treatment of small cell carcinoma of the lung in patients who are not candidates for potentially curative surgery and/or radiation therapy. | Bristol-Myers Squibb (M) Sdn. Bhd. 17th floor Menara Lien Hoe, 8 Persiaran Tropicana, 47410 PJ |

DCA 172 (28/7/2005)

| NO | | PRODUCT (ACTIVE | ADDITIONAL INDICATION | MARKETING AUTHORIZATION |
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| | | INGREDIENT) | | HOLDER |
|----|-------------------|---|---|---|
| 1. | 1.1 1.2 1.3 | Arava 10mg tablet Arava 20mg tablet Arava 100mg tablet (Leflunomide) | .Active psoriatic arthritis. | Aventis Farma SA (Malaysia) Sdn. Bhd. 8th. Floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights, 50490 KUALA LUMPUR |
| 2. | 2.1 | Prevacid capsules 30mg (Lansoprazole) | i) Relief of reflux-like symptoms (eg. heartburn) and/or ulcer-like symptoms (eg. upper epigastric pain) associated with acid-related dyspepsia. ii) Short-term treatment of symptomatic GERD and erosive esophagitis for children (12-17 years of age). | Zuellig Pharma Sdn. Bhd. Level 3A, Block B, No. 10 Jalan Bersatu 13/4, 46200 PJ |
| 3. | 3.1 | Tamiflu Capsule 75 mg (Oseltamivir Phosphate) | Full indications are as follows: Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza infection in patients aged 18 years and older who have been symptomatic for no more than 2 days. Treatment should commence as soon as possible but no later than forty-eight hours after the onset of the initial symptoms of infection. Post exposure prevention in adults and adolescents 13 years of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community. | Roche (M) Sdn. Bhd., Wisma Selangor Dredging, 142, Jalan Ampang, 50450 Kuala Lumpur. |

DCA 172

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-------------------|--|---|---|
| 1 | 1.1 1.2 1.3 | Taxol for Injection Concentrate, 30mg/5ml vial Taxol Injection 100mg/16.7ml vial Taxol Injection 300mg/50ml vial (Paclitaxel) | Breast carcinoma The initial treatment of advanced or metastatic breast cancer in combination with trastuzumab in patients who over-express HER-2 at a 3+ level as determined by immunohistochemistry and for whom an anthracycline is not suitable. For Taxol Injection 300mg/50ml vial, it is also indicated for: | Bristol-Myers Squibb (M) Sdn. Bhd. 17th floor Menara Lien Hoe, 8 Persiaran Tropicana, 47410 PJ |

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| | | <p>Ovarian carcinoma</p> <ul style="list-style-type: none"> - First-line therapy in combination with a platinum compound for the treatment of advanced metastatic carcinoma of the ovary. - Second-line therapy for the treatment of advanced metastatic carcinoma of the ovary. <p>Non-small cell lung carcinoma</p> <ul style="list-style-type: none"> - First-line therapy in combination with a platinum compound or as a single agent for the treatment of small cell carcinoma of the lung in patients who are not candidates for potentially curative surgery and/or radiation therapy. | |
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DCA 171 (30/6/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|------------|--|--|---|
| 1 | 1.1 1.2 | Taxotere 20mg/0.5ml vial Taxotere 80mg/2ml vial | <p>Prostate cancer</p> <p>Taxotere in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostatic cancer.</p> <p>Breast cancer</p> <p>Taxotere in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.</p> | <p>Aventis Farma SA (Malaysia) Sdn. Bhd.</p> <p>8th. Floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights, 50490 KUALA LUMPUR</p> |

DCA 170 (26/5/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|------------|--|---|--|
| 1. | 1.1 1.2 | Valtrex tablets 250mg Valtrex tablets 500mg (Valaciclovir hydrochloride) | <p>Valtrex can reduce transmission of genital herpes when taken as suppressive therapy and combined with safer sex practices (particularly the use of condoms).</p> | <p>GlaxoSmithKline Pharmaceutical Sdn. Bhd.</p> <p>8th floor, Menara Lien Hoe, 8 Persiaran Tropicana, 47410 Petaling Jaya, Selangor.</p> |
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| 2 | 2.1 2.2 | Eloxatin 50mg freeze dried powder for infusion Eloxatin 100mg freeze dried powder for infusion (Oxaliplatin) | Oxaliplatin in combination with 5-fluorouracil and folinic acid is indicated in: i) the adjuvant treatment of stage III colon cancer (Dukes stage C) following complete resection of the initial tumour ii) the treatment of metastatic colorectal cancer | Sanofi Synthelabo (Malaysia) Sdn. Bhd. 8th floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights |
| 3. | 3.1 3.2 | Nexium 20mg tablet Nexium 24mg tablet (Esomeprazole Magnesium Trihydrate) | Patients requiring continued NSAID therapy - healing of gastric ulcers associated with NSAID therapy - prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk. | AstraZeneca Sdn. Bhd. PO Box 1122 50740 Kuala Lumpur |
| 4 | 4.1 4.2 4.3 | Atacand Tablet 4 mg Atacand Tablet 8 mg Atacand Tablet 16 mg (Candesartan Cilexetil) | Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction = 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated. | AstraZeneca Sdn. Bhd. PO Box 1122 50740 Kuala Lumpur |
| 5. | 5.1 5.2 | Proscar 5mg tablet Proscar 5mg tablet (Finasteride) | Full indications: Proscar is indicated for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events to: - reduce the risk of acute urinary retention - reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy. Proscar causes regression of the enlarged prostate, improves urinary flow and improves the symptoms associated with BPH. Patients with enlarged prostate are the appropriate candidates for therapy with Proscar. Proscar administered in combination with the alpha-blocker doxazosin is indicated to reduce the risk of symptomatic progression of BPH (a confirmed 4 point increase in AUA symptom score). | Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th floor, Menara Merais, 1, Jln. 19/3, 46300 PJ. |
| 6. | 6.1 6.2 6.3 | Vfend IV 200mg/30ml Vfend 50mg Tablet Vfend 200mg Tablet | - Treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall and wounds. | Pfizer (M) Sdn. Bhd., Level 3 & 4, Bangunan Palm |

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| | (Voriconazole) | | Grove, No. 14, Jalan Glenmarie, (Persiaran Kerjaya), Section U1, 40150, Shah Alam, Selangor. |
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DCA 169 (28/4/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|--|--|--|---|
| 1. | 1.1 1.2 1.3 1.4 1.4 1.6 | Videx Paediatric Oral Suspension 2g Videx Paediatric Oral Suspension 4g Videx tablet 25mg Videx tablet 50mg Videx tablet 100mg Videx tablet 200mg (Didanosine) | For treatment of HIV-infected pediatric patients from 2 weeks of age and older in appropriate antiretroviral regimens in combination with other nucleoside analogues, non-nucleoside reverse-transcriptase inhibitors and HIV protease inhibitors. | Bristol-Myers Squibb (M) Sdn. Bhd. 16th floor, Menara Lien Hoe, 8, Persiaran Tropicana, 47410 PJ |
| 2 | 2.1 2.2 2.3 2.4 2. | Epilim Chrono 500mg tablet Epilim 200 enteric coated tablet Epilim 500 enteric coated tablet Epilim Syrup 200mg/5ml Epilim Liquid 200mg/5ml (Sodium valproate, valproic acid) | Treatment and prevention of mania associated with bipolar disorders. | Sanofi Synthelabo (Malaysia) Sdn. Bhd. 3.02 Level 3, Wisma Academy, Lot 4A, Jln 19/1, 46300 PJ |
| 3. | 3.1 | Valcyte tablet 450mg (Valganciclovir hydrochloride) | Valcyte is indicated for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor. | Roche (Malaysia) Sdn. Bhd. The Selangor Dredging, 142, Jalan Ampang, 50450 KL. |
| 4 | 4.1 | Femara 2.5mg film-coated tablet (Letrozole) | Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). | Novartis Corporation (Malaysia) Sdn. Bhd. Lot 9 Jalan 26/1, |

Seksyen 26,
Kaw. Perindustrian
HICOM,
40400 Shah Alam.

DCA 168 (21/3/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-------------------|--|--|---|
| 1 | 1.1 | Prevacid capsules 30mg (Lansoprazole) | Treatment and prophylaxis of NSAID-associated benign-gastric ulcers, duodenal ulcers and relief of symptoms in patients requiring continued NSAID treatment. | Zuellig Pharma Sdn. Bhd. Level 3A, Block B, No. 10 Jalan Bersatu 13/4, 46200 PJ |
| 2 | 2.1 2.2 2.3 | Imigran tablet 100mg Imigran tablet 50mg Imigran injection 6mg/0.5ml (Sumatriptan succinate) | Sumatriptan remains effective in treating menstrual migraine ie. migraine without aura that occurs between 3 days prior and up to 5 days post onset of menstruation. Sumatriptan should be taken as soon as possible in an attack. | GlaxoSmithKline Pharmaceutical Sdn. Bhd. 7th & 8th floor, Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya |

DCA 166 (31/1/2005)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|--------------------------|---|---|---|
| 1 | 1.1 1.2 | Gemzar for Injection 200mg Gemzar for Injection 1g (Gemcitabine) | Gemcitabine, in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma, who have relapsed >6 months, following platinum-based therapy. | Eli Lilly (Malaysia) Sdn. Bhd. Unit 18.1, Level 18, CP Tower, No. 11, Jln. 16/11, Pusat Dagang Seksyen 16, 46350 PJ |
| 2 | 2.1 2.2 2.3 2.4 | Lamictal 5mg dispersible tablet Lamictal 25mg dispersible tablet Lamictal 50mg tablet Lamictal 100mg tablet (Lamotrigine) | Bipolar disorder Adults (18 years of age and over) Lamotrigine is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes. | GlaxoSmithKline Pharmaceutical Sdn. Bhd. 7th & 8th floor, Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya |

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| 3 | 3.1 | Cancidas Injection | Cancidas is indicated for empirical therapy for presumed fungal infections in febrile, neutropenic patients. | Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th floor, Menara Merais, 1 Jln 19/3, Petaling Jaya |
| | 3.2 | 50mg/vial | | |
| | | Cancidas Injection 70mg/vial (Caspofungin acetate) | | |