

Year 2004

DCA 165 (16/12/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|------------|---|---|--|
| 1 | 1.1 1.2 | Efexor XR 75mg capsule Efexor XR 150mg capsule (Venlafaxine hydrochloride 75mg & 150mg) | Efexor XR is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia. | Wyeth (Malaysia) Sdn. Bhd. 701 & 801 Blok C, Kelana Business Centre, No. 97 Jalan SS 7/2, 47301 Petaling Jaya |

DCA 163 (14/10/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|--|--|--|--|
| 1 | 1.1 | Symbicort Turbuhaler 160/4.5mcg/dose (Budesonide & Formoterol) | Symptomatic treatment of patients with severe COPD (FEV1<50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. | AstraZeneca Sdn. Bhd. Wisma Prima 17 Jln Sri Semantan satu, Damansara Heights, 50490 KL |
| 2 | 2.1 2.2 | Oxis Turbuhaler 4.5mcg/dose Oxis Turbuhaler 9.0mcg/dose (Formoterol fumarate) | The relief of broncho-obstructive symptoms in patients with chronic obstructive pulmonary disease (COPD). | AstraZeneca Sdn. Bhd. Wisma Prima 17 Jln Sri Semantan satu, Damansara Heights, 50490 KL |
| 3 | 3.1 3.2 3.3 3.4 3.5 3.6 | Zithromax 250mg tablet (Italy) Zithromax 500mg tablet (Italy) Zithromax 600mg tablet (Italy) Zithromax powder for oral suspension 200mg/5ml Zithromax 250mg tablet (Australia) | i) Azithromycin is indicated in the treatment of chancroid due to Haemophilus ducreyi. ii) Azithromycin is indicated in combination with ethambutol for the treatment of disseminated Mycobacterium avium complex (DMAC) infections with advanced HIV infection. | Pfizer (Malaysia) Sdn. Bhd. Level 3&4Bangunan Palm Grove, No. 14 Jln Glenmarie, (Persiaran Kerjaya), Seksyen U1, 40150 Shah Alam, Selangor. |

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| | Zithromax 500mg tablet (Australia) | | |
| | (Azithromycin dehydrate) | | |

DCA 162 (9/9/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|------------|---|--|---|
| 1. | 1.1 | Xatral XL 10mg tablet (Alfuzosin hydrochloride) | Adjuvant treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy. | Sanofi Synthelabo (Malaysia) Sdn. Bhd. 3.02 Level 3, Wisma Academy, Lot 4A Jln. 19/1, 46300 PJ |
| 2. | 2.1 | Controloc 20mg tablet (Pantoprazole) | Prevention of gastrointestinal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAID) in patients at risk with a need for continuous NSAID treatment. | Diethelm (M) Sdn. Bhd, 74, Jln. Universiti, 46200 PJ |
| 3. | 3.1 3.2 | Taxotere 20mg/0.5ml Injection Taxotere 80mg/2ml Injection (Docetaxel) | Is indicated as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen. | Aventis Farma SA (M) S/B, 74, Jln Universiti, PO Box 77, 46700, P.Jaya, Selangor. |
| 4. | 4.1 | Forlax powder for oral solution (Macrogol) | Forlax 10g is indicated in symptomatic treatment of constipation in children aged 8 years and above. | Emerging Pharma Sdn. Bhd Phileo Damansara II, 3A03, Block B, Lot 15, Jln. 16/11, OFF Jln.. Damansara, 46300 PJ |

DCA 160 (1/7/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-----|---|---|---|
| 1. | 1.1 | Caelyx Concentrate for Infusion 2mg/ml (Doxorubicin hydrochloride) | Caelyx, as monotherapy, is indicated for the treatment of metastatic breast cancer. | Schering-Plough Sdn. Bhd. Level 3-1, CP Tower, 11 Jln. 16/11, Pusat Dagang |

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| | | | | Seksyen 16, 46350 Petaling Jaya, Selangor |
| 2. | 2.1 2.2 | Controloc IV Controloc 40 mg Tablet | Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions. | Diethelm Malaysia Sdn. Bhd., 74, Jalan University, 46200, Petaling Jaya, Selangor. |
| 3. | 3.1 | Botox (Botulinum Toxin Type A) IM Injection. | Botox is indicated for the management of severe hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirant or antihidrotics. | Diethelm Malaysia Sdn. Bhd., 74, Jalan University, 46200, Petaling Jaya, Selangor. |
| 4. | 4.1 4.2 | Gemzar for Injection 200 mg Gemzar for Injection 1 g | Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated | 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. |

DCA 159 (27/5/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|---------------------------------|---|---|--|
| 1. | 1.1 1.2 1.3 1.4 1.5 | Puregon solution for injection in vial 50IU/0.5ml Puregon solution for injection in vial 100IU/0.5ml Puregon solution for injection in vial 150IU/0.5ml Puregon solution for injection in cartridge 300IU Puregon solution for injection in cartridge 600IU (Follitropin beta) | In the male Deficient spermatogenesis due to hypogonadotropic hypogonadism. | Organon (M) Sdn. Bhd. Level 4, Building A, Paremba Square, Saujana Resort, Seksyen U2, 40150 Shah Alam, Selangor. |

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| 2 | 2.1 2.2 | Clozaril 25mg tablet Clozaril 100mg tablet (Clozapine) | Risk of recurrence suicidal behaviour Clozaril is indicated for reducing the risk of recurrent suicidal behaviour in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behaviour, based on history and recent clinical state. Suicidal behaviour refers to actions by a patient that put him/herself at high risk for death. | Novartis Corporation (Malaysia) Sdn. Bhd. LOT 9, Jln. 26/1, Seksyen 26, Kawasan Perindustrian HICOM 40400 Shah Alam, Selangor. |
| 3. | 3.1 3.2 | Zoloft 50mg tablet Zoloft 100mg tablet (Sertraline) | Treatment of social phobia (social anxiety disorder). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of social phobia. | Pfizer (Malaysia) Sdn. Bhd. Level 3 & 4, Bangunan Palm Grove, No.14 Jln. Glenmarie (Persiaran Kerjaya), Seksyen U1, 40150 Shah Alam, Selangor |
| 4. | 4.1 | Casodex 150mg tablet (Bicalutamide) | In patients with locally advanced prostate cancer, Casodex 150mg is indicated as immediate therapy either alone or as adjuvant to treatment by radical prostatectomy or radiotherapy. | AstraZeneca Sdn. Bhd. Wisma Prima 17, Jalan Sri Semantan Satu, Damansara Heights, 50490 Kuala Lumpur |
| 5 | 5.1 5.2 5.3 | Seroquel tablet 25mg Seroquel tablet 100mg Seroquel tablet 200mg (Quetiapine free base) | SEROQUEL is indicated for the short term treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex. | AstraZeneca Sdn. Bhd. Wisma Prima 17, Jln. Sri Semantan Satu, Damansara Heights, 50490 Kuala Lumpur |

DCA 158 (27/4/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
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| 1. | 1.1 | Lantus 100 IU/ml (3ml | Indicated for once-daily subcutaneous | Aventis Farma SA |

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| | | cartridge) 1.2 Lantus 100 IU/ml (10ml vial) 1.3 Lantus 100 IU/ml Optiset (Insulin glargine) | administration in the treatment of type 1 diabetes mellitus in adults and children (6 years or above) and type 2 diabetes mellitus in adults who require insulin for the control of hyperglycaemia. | (M)Sdn. Bhd. 74, Jln. Universiti, 46200 PJ |
| 2 | 2.1 2.2 | Rapamune tablet 1mg Rapamune Oral Solution 1mg/ml (Sirolimus) | It is recommended that Rapamune be used initially in a regimen with cyclosporine and corticosteroids. Cyclosporine withdrawal may be considered 2 to 4 months after transplantation in patients at low to moderate immunological risk. Therapeutic drug monitoring of sirolimus is required. The final proposed indication will be as follows: Rapamune is indicated for the prophylaxis of organ rejection in patients receiving renal transplants. It is recommended that Rapamune be used initially in a regimen with cyclosporine and corticosteroids. Cyclosporine withdrawal may be considered 2 to 4 months after transplantation in patients at low to moderate immunological risk. Therapeutic drug monitoring of sirolimus is required. | Wyeth (M) Sdn. Bhd. 701 & 801, Blok C (Menara Glomac), Kelana Jaya Business Centre, No. 97, Jln. SS 7/2, 47301 Kelana Jaya, PJ |
| 3. | 3.1 | Enbrel injection 25mg/vial (Etanercept) | Indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. | Wyeth (M) Sdn. Bhd. 701 & 801, Blok C (Menara Glomac), Kelana Jaya Business Centre, No. 97, Jln. SS 7/2, 47301 Kelana Jaya, PJ |
| 4. | 4.1 4.2 | Glivec 50mg capsule Glivec 100mg capsule (Imatinib mesylate) | - For newly diagnosed adult patients with Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) in chronic phase whom bone marrow transplant is not considered as the first line of treatment. - For the treatment of paediatric patients with Ph+CML in chronic phase, whose disease has | Novartis Corporation (M) Sdn. Bhd. Lot 9, JLn 26/1, Seksyen 26, Kaw. Perindustrian HICOM, 40400 |

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| | | | <p>reccurred after stem cell transplantation or who are resistant to interferon alpha therapy.</p> <p>The final indication will be as follows:</p> <ul style="list-style-type: none"> - Indicated for the treatment in patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) in chronic phase whom bone marrow transplant is not considered as the first line of treatment, as well as for the treatment of patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy or in accelerated phase or blast crisis. - Glivec is indicated for the treatment of paediatric patients with Ph+CML in chronic phase, whose disease has recurred after stem cell transplantation or who are resistant to interferon alpha therapy. - Also indicated for the treatment of adult patients with unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). <p>The effectiveness of Glivec is based on overall haematological and cytogenic response rates and progression-free survival in CML and objective response rates in GIST. There are no controlled trials demonstrating increased survival for either of the two disease.</p> <p>The effectiveness of Glivec is based on overall haematological and cytogenic response rates and progression-free survival in CML and objective response rates in GIST. There are no controlled trials demonstrating increased survival for either of the two disease.</p> | Shah Alam |
| 5. | 5.1 5.2 5.3 | <p>Zyprexa 5mg tablet</p> <p>Zyprexa 7.5mg tablet</p> <p>Zyprexa 10mg tablet</p> <p>(Olanzapine)</p> | <p>Olanzapine is indicated for preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.</p> | <p>Eli Lilly (M) Sdn. Bhd.</p> <p>Unit 18.1, Level 18, CP Tower, No.11, Jln. 16/11, Pusat Dagang Seksyen 16, 46350 Petaling Jaya</p> |
| 6. | 6.1 | <p>Seretide Accuhaler 50/250mcg</p> | <p>Seretide is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD)</p> | <p>GlaxoSmithKline</p> |

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| | 6.2 | Seretide Accuhaler 50/500mcg (Salmeterol xinafoate & Fluticasone propionate) | including chronic bronchitis and emphysema. | Pharmaceuticals Sdn. Bhd. 7th & 8th floor, Menara Lien Hoe, 8 Persiaran Tropicana, 47410 PJ |
| 7. | 7.1 | Seroxat 20mg tablet (Paroxetine hydrochloride 20mg) | Prevention of relapse of obsessive compulsive disorder (OCD). -Prevention of relapse of panic disorder with or without agoraphobia. | GlaxoSmithKline Pharmaceuticals Sdn. Bhd. 7th & 8th floor, Menara Lien Hoe, 8 Persiaran Tropicana, 47410 PJ |
| 8. | 8.1 | Actilyse Treatment Set 50mg/vial, (powder and solvent for solution for injection) (Alteplase 50mg) | Thrombolytic treatment of acute ischaemic stroke. Treatment should only be initiated within 3 hours after the onset of stroke symptoms and after exclusion of intracranial hemorrhage by appropriate imaging techniques such as cranial computerized tomography (CT). | Boehringer Ingelheim (M) Sdn. Bhd. 2d floor, Wisma UEP, Jln. USJ 10/1A, PO Box 3031, 47590 Subang Jaya, Selangor |

DCA 155 (27/1/2004)

| NO | | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|-------------------|--|--|--|
| 1. | 1.1 1.2 | Diovan 80mg tablet Diovan 160mg tablet (Valsartan) | Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (eg. diuretics, digitalis) who are intolerant to ACE inhibitors. | Novartis Corporation (M) Sdn. Bhd. Lot 9, JLn 26/1, Seksyen 26, Kaw. Perindustrian HICOM, 40400 Shah Alam |
| 2 | 2.1 2.2 2.3 | Lescol 20mg capsule Lescol 40mg capsule Lescol XL 80mg tablet (Fluvastatin) | i) To reduce the rate of progression of atherosclerosis in patients with coronary artery disease and mild to moderate elevations of cholesterol as part of a treatment strategy to lower total and LDL cholesterol to target levels. | Novartis Corporation (M) Sdn. Bhd. Lot 9, JLn 26/1, Seksyen 26, Kaw. Perindustrian |

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| | | | ii) Indicated in patients with coronary heart disease for the secondary prevention of coronary events after percutaneous coronary intervention. | HICOM, 40400 Shah Alam |
| 3. | 3.1 3.2 | Ciprobay tablet 250mg Ciprobay tablet 500mg (Ciprofloxacin) | Treatment of inhalation anthrax (post-exposure) in adults and children: To reduce the incidence or progression of disease following exposure to aerolised Bacillus anthracis | Bayer (M) Sdn. Bhd. Suite 2.05, 2nd floor, Blok B, 10, Jln. Bersatu 13/4, 46200 PJ, Selangor |
| 4. | 4.1 4.2 4.3 | Singulair 5mg chewable tablet Singulair 10mg tablet Singulair 4mg chewable tablet (Montelukast) | It is indicated in adults 15 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis. The dosage:- Adults 15 years of age and older with allergic rhinitis The dosage is one 10mg tablet daily. | Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th floor, Menara Merais, 1 Jln 19/3, PJ |