

Year 1999

DCA 111 (23/12/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1. Recormon 1000 iu 2. Recormon 2000 iu 3. Recormon 5000 iu 4. Recormon 10000 iu Epoetin Beta (recombinant human erythropoietin)	<ul style="list-style-type: none">• Prevention of anaemia of prematurity in infants with a birth weight of 750 to 1500 g born before the 34th weeks of pregnancy.• Treatment of anaemia in adult patients with solid tumors receiving platinum-based chemotherapy that commonly causes anaemia	Roche (M) S/B
2.	1. Ticlid Film-Coated Tablet 250 mg (Ticlopidine Hydrochloride)	<ul style="list-style-type: none">• Prevention of subacute occlusions following coronary stents(s) implantation	Sanofi (M) S/B

DCA 110 (25/11/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1. Mobic Tablet 7.5 mg 2. Mobic Tablet 15 mg 3. Mobic Capsule 7.5 mg 4. Mobic Capsule 15 mg 5. Mobic Suppository 15 mg	<ul style="list-style-type: none">• Ankylosing spondylitis	Boehringer Ingelheim (M) S/B
2.	1. Trivastal Retard 50 mg	<ul style="list-style-type: none">• Adjunctive symptomatic treatment of chronic pathological cognitive and neurosensorial deficit in elderly subjects (excluding Alzheimers disease and other dementia)	Servier (M) S/B

DCA 109 (28/10/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
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1.	<ol style="list-style-type: none"> 1. Serevent Inhaler 25 mcg 2. Serevent Accuhaler 50 mcg 3. Serevent Rotadisk 50 mcg 	<ul style="list-style-type: none"> • Serevent inhaler / accuhaler / rotadisk can be used to treat reversible airways obstruction in patients requiring long-term regular bronchodilator therapy, including those with asthma and with Chronic Obstructive Pulmonary Disease (COPD) 	<p>Allen & Hanburgs Sdn. Bhd.,</p> <p>Petaling jaya</p>
2.	<ol style="list-style-type: none"> 1. Lariam 250 mg Tablet 	<ul style="list-style-type: none"> • <u>Prophylaxis.</u> • Chemoprophylaxis with Lariam is recommended for travellers to malarious areas, particularly those travelling to areas where there is a high risk of infections with strains of <i>P. falciparum</i> resistant to other antimalarials. 	<p>Roche (M) Sdn. Bhd.,</p> <p>Kuala Lumpur</p>

DCA 107 (26/8/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	<ol style="list-style-type: none"> 1. Zoloft 50 mg (Australia) 2. Zoloft 100 mg (Australia) 3. Zoloft 50 mg (UK) 4. Zoloft 100 mg (UK) <p>(Setraline 50 mg)</p>	<ul style="list-style-type: none"> • Panic Disorder 	<ol style="list-style-type: none"> 1. Pfizer Pty. Ltd., Australia 2. Pfizer Pty. Ltd., Australia 3. Pfizer Pty. Ltd., UK 4. Pfizer Pty. Ltd., UK
2.	<ol style="list-style-type: none"> 1. Pentasa Slow Release Tablet 250 mg 2. Pentasa Slow Release Tablet 500 mg <p>(Mesalazine)</p>	<ul style="list-style-type: none"> • Maintenance therapy for patients with Crohns Disease in remission induced by surgery or medication 	<ol style="list-style-type: none"> 1. United Italian Trading (M) S/B, Selangor 2. United Italian Trading (M) S/B, Selangor
3.	Hycamtin 4 mg Injection	<ul style="list-style-type: none"> • Treatment of patients with small cell lung carcinoma (after failure of first line chemotherapy) 	SmithKline Beecham, S/B
4.	<ol style="list-style-type: none"> 1. ReoPro Injection 10 mg/5 ml 	<ul style="list-style-type: none"> • <u>Percutaneous coronary intervention</u> 	<ol style="list-style-type: none"> 1. Eli Lilly (M) S/B 2. Eli Lilly (M) S/B

	<p>2. ReoPro Injection 40 mg/20 ml (Abciximab 2mg/ml)</p>	<p>The prevention of ischaemic cardiac complication in patients undergoes percutaneous coronary intervention (balloon angioplasty, atherectomy and bailout stent)</p> <p>(This indication will replaced current approved indication Aciximab is indicated as and adjunct to heparin and aspirin for the prevention of ischaemic cardiac complications in high risk patients undergoing percutaneous transluminal coronary antioplasty or artherectomy (PTCA))</p> <ul style="list-style-type: none"> • <u>Unstable Angina</u> <p>The short term (1-month) reduction of risk of myocardial infarction, in patients with unstable angina, not responding to full convention therapy who have been scheduled for percutaneous coronary intervention</p>	
4	<p>Gemzar 100 mg (Gemcitabine Hydrochloride)</p>	<ul style="list-style-type: none"> • Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer 	<p>Eli Lilly (M) S/B, P. Jaya</p>

DCA 105 (24/6/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	<p>a. Sufenta Forte Ampoule 0.05 Mg/MI b. Sufenta Ampoule 0.005</p>	<ul style="list-style-type: none"> • For the post operative management of pain following general surgery, thoracic or 	<p>Johnson & Johnson S/B</p>

	Mg/ml (10 ml) Injection	<p>orthopaedic procedures and caesarean section.</p> <ul style="list-style-type: none"> • as an analgesic adjunct to epidural bupivacaine during labour and vaginal deliveries 	
2.	Valtrex Tablet 500 Mg	<ul style="list-style-type: none"> • Valtrex can prevent lesion development when taken at the first signs and symptoms of an HSV recurrence. • Valtrex is indicated for the prevention (suppression) of recurrent herpes simplex infections of the skin and mucous membranes, including genital herpes. 	Allen & Hanburys S/B, Selangor

DCA 104 (27/5/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	Azep Nasal Spray (Azelastine Hydrochloride)	For symptomatic treatment of perennial allergic rhinitis in children 12 years and above	Zuellig Pharma (M) Sdn. Bhd.
2.	Gemzar 200 Mg (Gemcitabine Hydrochloride)	Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer	Eli Lilly (M) S/B, PJ
3.	Zestril 5 Mg, 10 Mg, 20 Mg (Lisinopril)	<u>Renal Complications of Diabetes Mellitus</u> In normotensive insulin-dependent and hypertensive non-insulin dependent diabetes mellitus patients who have incipient nephropathy characterised by microalbuminuria, Zestril reduces urinary excretion rate	Zeneca Pharma malaysia
4.	Clexane 20 Mg/0.2 ml PFS Clexane 40 Mg/0.4 ml PFS Clexane 60 Mg/0.6 ml PFS Clexane 80 Mg/0.8 ml PFS	Treatment of unstable angina Non-Q-wave Myocardial Infarction During the Acute Phase in combination with aspirin	Rhone-Poulenc Rorer Malaysia S/B, PJ

Clexane 100 Mg/ml PFS
(Enoxaparine Sodium)

DCA 103 (15/4/1999)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	Zocor 5, 10, 20 mg Tablet (Simvastatin)	Hyperlipidaemia- Zocor is indicated as adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B and triglycerides in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, or combined (mixed) hyperlipidaemia when response to diet and other nonpharmacological measures is inadequate	MerckSharp & Dohme (I.A.) Corp. Selangor
2.	Fosamax 10 mg Tablet (Sodium Alendronate)	For the treatment of osteoporosis in post-menopausal women. Fosamax increases bone mass and prevent fractures, including those of hip and spine (Vertebral compression fractures). Osteoporosis may be confirmed by the finding of low bone mass or by the presence of history of osteoporotic fracture	MerckSharp & Dohme (I.A.) Corp. Selangor

DCA 102 (25/2/1999)

No.	Product (active ingredient)	Additional Indication	Product Registration Holder
1.	Pravachol Tablet 10mg, 20 mg (Pravastatin Sodium)	Myocardial Infarction: in patients with previous myocardial infarction and average (normal) serum cholesterol levels, PRAVACHOL is indicated to reduce the risk of recurrent myocardial infarction, need for myocardial revascularization procedures and to reduce the risk of stroke or transient attacks (TIAs).	Bristol-Myers Squibb (M) Sdn. Bhd.

DCA 101 (28/1/1999)

No.	Products	Additional Indication	Product Registration Holder

1.	Botox (Botulinum Toxin A 100 IU)	Treatment of strabismus and blepharospasm associated with dystonia, including essential blepharospasm or VII nerve disorders in patients 12 years and above.	Zuellig Pharma Sdn. Bhd.
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