

Year 2000

DCA 120 (21/12/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1. Gemzar 200 Mg Injection 2. Gemzar 1G Injection (Gemcitabine Hydrochloride)	Bladder cancer at invasive stage	Eli Lilly (M) S/B
2.	1. Duphaston 10 Mg Tablet (Dydrogesterone)	<ul style="list-style-type: none">• <u>Hormone replacement therapy</u> To counteract the effects of unopposed oestrogen on the endometrium in hormone replacement therapy for women with disorders due to natural or surgical induced menopause with an intact uterus.	Faulding Pharmaceuticals (M) S/B

DCA 119 (30/11/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1. Losec Mups 10 Mg 2. Losec Mups 20 Mg (Omeprazole Magnesium)	Acid related dyspepsia - Additional information to be included under " <u>Mode of Administration</u> " • Patients who do not respond after 4 weeks or who relapsed shortly afterwards, should be investigated	Astra pharmaceutical (Malaysia) S/B, KL
2.	1. Sporanox Oral Solution 10 mg/ml (Itraconazole)	As prophylaxis of deep fungal infections when standard therapy is considered inappropriate in patients with haematological malignancy or undergoing bone marrow transplant, and who are expected to become neutropenic (i.e. <500 cell/m l) - Additional note to be included under " <u>Therapeutic Indications</u> "	Johnson & Johnson S/B, PJ

		<ul style="list-style-type: none"> At present there are insufficient data on clinical efficacy in the prevention of aspergillosis 	
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DCA 118 (24/10/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	Prozac 20 mg Capsules (Fluoxetine 20 mg)	Pre-menstrual Dysphoric Disorder (PMDD)	Eli Lilly (M) S/B
2.	Carboplatin Injection 450 mg/45 ml Carboplatin Injection 150 mg/15 ml (Carboplatin)	<ul style="list-style-type: none"> Small cell lung carcinoma Carcinoma of head and neck 	Faulding Pharmaceuticals (M) S/B
3.	Botox [®] (Botulinum Toxin Type A) IM Injection (Botulinum Toxin Type A)	In the management of abnormal gait due to increased muscle tone associated with cerebral palsy in patients, two years of age or older	Diethelm Malaysia S/B
4.	Evista Film Coated Tablet (Raloxifene Hydrochloride)	Treatment of osteoporosis in post menopausal women	Eli Lilly (M) S/B
5.	Genotropin 4 IU Genotropin 16 IU Genotropin 36 IU (Somatropin)	Replacement therapy in adults with pronounced growth hormone deficiency	Zuellig Pharma S/B
6.	Venoglobulin S 5% Solution (Human Immunoglobulin G50 mg/ml)	Kawasaki disease	Alpha Therapeutic (M) S/B

DCA 116 (27/07/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	I. Emla Cream 5% II. Emla patch (Lidocaine & Prilocaine)	For use in neonates (0-3 months of age)	Astra Pharmaceutical (M) S/B

DCA 115 (25/5/2000)

No.	Product (Active	Additional Indication	Product
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	Ingredient)		Registration Holder
1.	Zoladex Depot Injection (goserelin/GnRH Analogue 3.6 mg/depot)	<u>Assisted reproduction:</u> Pituitary down regulation in preparation for superovulation	Zeneca Pharma (M) S/B
2.	1. Taxol For Injection 30 mg/vial 2. Taxol For Injection 100 mg/vial (Paclitaxel)	1. <u>Ovarian Carcinoma</u> First line therapy in combination with a platinum compound for the treatment of advanced metastatic carcinoma of the ovary. 2. <u>Non-Small Cell Lung Carcinoma</u> First line therapy in combination with a platinum compound for the treatment of non-small cell carcinoma of the lung in patients who are not candidates for potentially curative surgery and/or radiation therapy.	Bristol-Myers Squibb (Malaysia) S/B
3	1. Topamax Tablet 25 Mg 2. Topamax Tablet 50 Mg 3. Topamax Tablet 100 Mg 4. Topamax Tablet 200 Mg (Topiramate)	As Adjunct therapy for pediatric patients (2 years and above) with partial onset seizures.	Johnson & Johnson (M) S/ B

DCA 114 (27/4/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	1. Campto 40 Mg/2 MI Injection 2. Campto 100 Mg/5 MI Injection (Irinotecan Hydrochloride Trihydrate)	Treatment of patients with advanced colorectal cancer: <ul style="list-style-type: none"> • In combination with 5-Fluorouracil and Folinic acid in patients without prior chemotherapy for advanced disease. 	Rhone-Poulence Rorer (M) S/B
2.	Lucrin Depot 3.75 Mg Injection (Leuprolide Acetate 3.75 mg)	Leuprolide Acetate for Depot Suspension is indicated in the treatment of children with central precocious puberty (CPP). Children should be selected using the following criteria:-	Abbott laboratories Malaysia

		<ol style="list-style-type: none"> 1. Clinical diagnosis of CPP (idiopathic or neurogenic) with onset of secondary sexual characteristics earlier than eight years in females and nine years in males. 2. Clinical diagnosis should be confirmed prior to initiation of therapy:- <ul style="list-style-type: none"> • Confirmation of diagnosis by a pubertal response to a GnRH stimulation test. The sensitivity and methodology of this assay must be understood. • Bone age advanced one year beyond the chronological age. 3. Baseline evaluation should also include:- <ul style="list-style-type: none"> • Heights and weight measurements. • Sex steroid levels. • Adrenal steroid level to exclude congenital adrenal hyperplasia. • Beta human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumour. • pelvic/adrenal/testicular ultrasound to rule out a steroid secreting tumour. • Computerized tomography of the head to rule out intracranial tumour. <ul style="list-style-type: none"> ▪ To include into package insert under the heading "For Pediatric Use". 	
3.	1. Esmeron Injection 50 mg/5 ml (ampoules)	<ul style="list-style-type: none"> • Esmeron is indicated as an adjunct to general anesthesia to facilitate 	Organon (M) S/B

	2. Esmeron Injection 100 mg/10 ml (ampoules) (Rocuronium)	endotracheal intubation, to provide skeletal muscle relaxation and to facilitate mechanical ventilation in adults, children and infants from <u>one</u> month of age.	
4	1. Reopro Injection 10 Mg/5 MI 2. Reopro Injection 40 Mg/20 MI (Abciximab 2 mg/ml)	Abciximab is indicated as an adjunct to heparin and aspirin for: a. <u>Percutaneous coronary intervention:</u> The prevention of ischaemic cardiac complication in patients undergoing percutaneous coronary intervention (balloon angioplasty, atherectomy and bailout stent). b. <u>Unstable Angina:</u> 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.	Eli Lilly (M) S/B
5	Trexan Tablet 50 Mg (Naltrexone Hydrochloride 50 mg)	In the treatment of alcohol dependence Trexan has not been shown to provide any therapeutic benefit except as part of an appropriate plan of management for the addictions.	The Boots Company (Malaysia) S/B

DCA 112 (27/1/2000)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1.	a. Cellcept® 500 mg Tablet b. Cellcept® 250 mg Tablet (Mycophenolate Mofetil)	<ul style="list-style-type: none"> Prophylaxis of organ rejection inpatients receiving allogenic <u>cardiac transplant</u>. It should be used concomitantly with cyclosporin and corticosteroids. 	Roche (M) S/B
2.	Seroxat 20 Tablet (Paroxetine HCl 20 mg)	<ul style="list-style-type: none"> Treatment of Social Anxiety Disorder/Social Phobia 	SmithKline Beecham S/B
3.	a. Esmeron Injection 50 mg/5 ml (ampoules) b. Esmeron Injection 100 mg/5	<ul style="list-style-type: none"> To facilitate mechanical ventilation as part of Rapid Sequence Induction in ICU, however, this has not been 	Organon (M) S/B

ml (ampoules)

studied in infants and children

c. Esmeron Injection 50 mg/5
ml (vials)

d. Esmeron Injection 100
mg/10 ml (vials)

e. Esmeron Injection 250
mg/25 ml (vials)

(Rocuronium)