

Year 2000

DCA 120 - 21/12/2000

(Last updated on 29th May 2001)

No.	Product	Active Ingredient	Product Registration Holder
1.	Blopress Tablets 8 Mg	Candesartan Cilexetil 8 mg	Zuellig Pharma S/B Packer: PT Takeda Indonesia
2.	Blopress Tablets 16 Mg	Candesartan Cilexetil 16 mg	Zuellig Pharma S/B
3.	Telebrix 35-50 MI (350 mg/ml) Solution for Injection	Meglumine Ioxitalamate 32.54 g Sodium Ioxitalamate 4.83 g	Ken-Med S/B

DCA 119 - 30/11/2000

(Last updated on 29th May 2001)

No.	Product	Active Ingredient	Product Registration Holder
1.	Viramune Oral Suspension 50 mg/5 ml	Nevirapine Hemihydrate 51.750 mg/5 ml	Boehringer Ingelheim (CM) S/B

DCA 118 - 24/10/2000

(Last updated on 12th February 2001)

No.	Product	Active Ingredient	Product Registration Holder
1.	Betaferon Injection	Recombinant Interferon beta- 1b 0.3 mg/vial	Zuellig Pharma S/B
2.	Targocid 200 mg Injection	Teicoplanin 200 mg	AgrEvo HS Malaysia S/B

DCA 117 (24/08/2000)

(Last Updated on 03rd January 2001)

No.	Product (Active Ingredient)	Additional Indication	Product Registration Holder
1	1. Anzatax Injection Concentrate 30 mg/5 ml 2. Anzatax Injection Concentrate 150 mg/5 ml (Paclitaxel)	The primary treatment of advanced ovarian cancer in combination with a platinum agent	Faulding Pharm (M) S/B

2	<p>3. Humalog 1.5 ml Cartridge 4. Humalog 3.0 ml Cartridge 5. Humalog 10 ml Vial</p> <p>(Insulin Lispro)</p>	Post Prandial Administration	Eli Lilly (Malaysia) S/B
3	<ul style="list-style-type: none"> • Cataflam Tablet 50 mg <p>(Diclofenac Potassium)</p>	<p>Short-term treatment in acute migraine attacks</p> <ul style="list-style-type: none"> • Should include the following in the package insert <p>"Diclofenac Potassium should be used for migraine prophylaxis"</p>	Novartis Corporation (M) S/B
4	<p>7. Meronem IV 500 mg vial 8. Meronem IV 1000 mg vial</p> <p>(Meropenem)</p>	<p>Meronem IV 500 mg</p> <ul style="list-style-type: none"> • Empiric treatment for pressured infections in adult patients and children with febrile neutropenia, used as monotherapy or combination with anti-viral and anti fungal agents • Complicated UTIS • Gynaecological <p>Meronem IV 1000 mg</p> <ul style="list-style-type: none"> • Bacterial septicaemia 	Zeneca Pharma (M) S/B
5	<ul style="list-style-type: none"> • Ethyol Lyophilized Powder for Injection 500 mg/10 ml <p>(Amifostine)</p>	<p><u>Radiotherapy</u></p> <p>Ethyol is indicated, in association with standard fractionated radiation therapy, to protect against acute and late xerostomia, in head and neck cancer.</p>	Schering-Plough S/B
6	<p>10. Fraxiparine Inj. 0.2 ml (Nadroparin Calcium 5,000 Cl.Axa/0.2 ml) 11. Fraxiparine Inj. 0.3 ml (Nadroparin Calcium 7,500 Cl.Axa/0.3 ml) Fraxiparine Inj. 0.4 ml (Nadroparin Calcium 10,000 Cl.Axa/0.4 ml) 12. Fraxiparine Inj. 0.6</p>	Treatment of unstable angina and a non-Q wave myocardial infarction during acute phase, in combination with aspirin	Sanofi-Synthelabo (M) S/B

	ml (Nadroparin Calcium 15,000 Cl.Axa/0.6 ml) Fraxiparine Inj. 0.8 ml (Nadroparin Calcium 20,000 Cl.Axa/0.8 ml) 13. Fraxiparine Inj. 1.0 ml (Nadroparin Calcium 25,000 Cl.Axa/1.0 ml)	
--	---	--

DCA 116 (27/07/2000)

(Last Updated on 20th November 2000)

No.	Product	Active Ingredient	Product Registration Holder
1.	Differin Gel 0.1%	Adapalene 0.1 G W/W	Summit Company (M), Selangor
2.	Zomig 2.5 Mg Tablet	Zolmitriptan 2.5 mg	Zeneca Pharma Malaysia
3.	Zomig 5 Mg Tablet	Zolmitriptan 5 mg	Zeneca Pharma Malaysia
4.	Seroquel 25 Mg Tablet	Quetiapine Fumarate 25 mg	Zeneca Pharma Malaysia
5.	Seroquel 100 Mg Tablet	Quetiapine Fumarate 100 mg	Zeneca Pharma Malaysia
6.	Seroquel 200 Mg Tablet	Quetiapine Fumarate 200 mg	Zeneca Pharma Malaysia
7.	Mizollen Tablet 10 Mg	Mizolastine 10.0 mg	Zuellig Pharma S/B, Selangor
8.	Cirrus Capsule	a. Cetirizine Dihydrochloride 5 mg b. Pseudoephedrine Hydrochloride 120 mg	Astra Pharmaceutical (M) S/B
9.	Atacand 4 Mg Tablet	Candesartan Cilexetil 4 mg	Astra Pharmaceutical (M) S/B
10.	Atacand 8 Mg Tablet	Candesartan Cilexetil 8 mg	Astra Pharmaceutical (M) S/B
11.	Atacand 16 Mg Tablet	Candesartan Cilexetil 16 mg	Astra Pharmaceutical (M) S/B
12.	Levovist 2.5 G Granulates; 20 MI Injection	Galactose 999 mg Palmitic Acid 1 mg (per 1 G Granules)	Zuellig Pharma (M) S/B
13.	Levovist 4.0 G Granulates;	Galactose 999 mg	Zuellig Pharma (M) S/B

20 MI Injection	Palmitic Acid 1 mg (per 1 G Granules)
-----------------	--

DCA 115 (25/5/2000)

(Last Updated on 18th September, 2000)

No.	Product	Active Ingredient	Product Registration Holder
1.	Fragmin 10,000 IU/ML 1 ml Ampoule	Dalteparin Sodium)	Zuellig Pharma S/B
2.	Fragmin 2,500 IU/ML 4 ml Ampoule	Dalteparin Sodium	Zuellig Pharma S/B
3.	Fragmin 2,500 IU/0.2 ML Single Dose Syringe	Dalteparin Sodium	Zuellig Pharma S/B
4.	Fragmin 5,500 IU/0.2 ML Single Dose Syringe	Dalteparin Sodium	Zuellig Pharma S/B
5.	Novo Norm 0.5 Mg Tablet	Repaglinide 0.5 mg	Novo Nordisk Pharma S/B
6.	Novo Norm 1 Mg Tablet	Repaglinide 1.0 mg	Novo Nordisk Pharma S/B
7.	Novo Norm 2.0 Mg Tablet	Repaglinide 2.0 mg	Novo Nordisk Pharma S/B
8.	Nasonex Aqueous Nasal Spray	Mometasone Furoate Monohydrate	Schering-Plough S/B
9.	Zalain Cream	Sertaconazole Nitrate 2 G	Wellmex S/B
10.	Mycospor Shampoo	Bifonazole	Bayer Malaysia S/B
11.	Alpagan Ophtalmic Solution 0.2%	brimonidine Tartrate 0.2% W/V	Diethelm (M) S/B
12.	Ziagen Oral Solution	Abacavir Sulfate 23.4 mg	Allen & Hansbury S/B
13.	Ziagen Tablet	Abacavir Sulfate 300 mg	Allen & Hansbury S/B
14.	Telebrix 30 Meglumine 30 MI (300 mg l/ml)	Meglumine Ioxitalamate 0.66 g/ml	Ken-Med Sdn. Bhd.
15.	Telebrix 30 Meglumine 100 MI	Meglumine Ioxitalamate 0.66 g/ml	Ken-Med Sdn. Bhd.
16.	Rebif 3 MIU/vial	Human Beta-Recombinant ? 1a (11 mcg)	Antah Pharma S/B

DCA 114 (27/4/2000)

(Last Updated on 4th May, 2000)

New Products Approved (Conditional approval)

No.	Product	Active Ingredient	Product Registration Holder
1.	Accolate 20 Mg Tablet	Zafirlukast 20 mg	Zeneca Pharma c/o Diethelm

2.	Sifrol Tablet 0.125 Mg	Pramipexole Monohydrate	Dihydrochloride	Boehringer (Malaysia) S/B	Ingelheim
3.	Sifrol Tablet 0.25 Mg	Pramipexole Monohydrate	Dihydrochloride	Boehringer (Malaysia) S/B	Ingelheim
4.	Sifrol Tablet 1.0 Mg	Pramipexole Monohydrate	Dihydrochloride	Boehringer (Malaysia) S/B	Ingelheim

DCA 113 (4/4/2000)

(Last Updated on 3rd May, 2000)

New Products Approved

No.	Product	Active Ingredient	Product Registration Holder
1.	Co-Diovan Tab	Valsartan 80 Mg Hydrochlorothiazide 12.5 mg	Novartis Corp. (M) S/B
2.	Fosamax 5 Mg Tablet	Alendronate Sodium 6.53 mg equivalent to 5 mg of Alendronate free acid	Merck Sharp & Dohme (I.A) Corp.
3.	Telfast 60 Mg Capsule	Fexofenadine HCl 60.0 mg	AgrEvo H.S. (M) S/B
4.	Maxalt Tablet 5 Mg	Rizatriptan Benzoate 7.265 mg	Merck Sharp & Dohme (I.A) Corp.
5.	Maxalt Tablet 10 Mg	Rizatriptan Benzoate 14.530 mg	Merck Sharp & Dohme (I.A) Corp.
6.	Maxalt Melt 15 Mg	Rizatriptan Benzoate 7.265 mg	Merck Sharp & Dohme (I.A) Corp.
7.	Maxalt Melt 10 Mg	Rizatriptan Benzoate 14.53 mg	Merck Sharp & Dohme (I.A) Corp.
8.	Okacine Eye Drops 5.0 MI	Lomefloxacin 3 mg (as Hydrochloride 3.31 mg)	Novartis Corp. (M) S/B
9.	Regranex Gel 0.01%	Becaplermin 0.01%	Johnson & Johnson S/B
10.	Syscor CC - 10 Mg Tablet	Nisoldipine	Zeneca Pharma (M) S/B
11.	Syscor CC - 20 Mg Tablet	Nisoldipine	Zeneca Pharma (M) S/B
12.	Syscor CC - 30 Mg Tablet	Nisoldipine	Zeneca Pharma (M) S/B
13.	Syscor CC - 40 Mg Tablet	Nisoldipine	Zeneca Pharma (M) S/B
14.	Vioxx Tablet 12.5 Mg	Rofecoxib	Merck Sharp & Dohme (I.A) Corp
15.	Vioxx Tablet 25 Mg	Rofecoxib	Merck Sharp & Dohme (I.A) Corp
16.	Vioxx Oral Suspension 12.5 Mg/5 MI	Rofecoxib	Merck Sharp & Dohme (I.A) Corp
17.	Vioxx Oral Suspension 25 Mg/5 MI	Rofecoxib	Merck Sharp & Dohme (I.A) Corp

DCA 112 (27/1/2000)(Last Updated on 7th March, 2000)

No.	Product	Active Ingredient	Product Registration Holder
1.	Xeloda 150 mg Tablet	Capecitabine 150 mg	Roche (M) S/B
2.	Xeloda 500 mg Tablet	Capecitabine 500 mg	Roche (M) S/B
3.	Refludan Injection	Lepirudin 50 mg	AgreEVO H.S. (M) S/B
4.	Celebrex 100 mg Capsule	Celecoxib	Monsanto (M) S/B
5.	Celebrex 200 mg Capsule	Celecoxib	Monsanto (M) S/B
6.	Avandia 2 mg Tablet	Rosiglitazone Maleate	SmithKline Beecham S/B
7.	Avandia 4 mg Tablet	Rosiglitazone Maleate	SmithKline Beecham S/B
8.	Avandia 8 mg Tablet	Rosiglitazone Maleate	SmithKline Beecham S/B
9.	Aldara Cream 5%	Imiquimod	3M Malaysia S/B
10.	Zerit Powder For Oral Solution 1 mg/ml	Stavudine	Bristol-Myers Squibb (M) S/B