

## Year 1999

### DCA 111 (23/12/99)

(Last Updated on 31<sup>st</sup> December 1999)

No.	Product	Active Ingredient	Product Registration Holder
1.	Xenical 120 mg Capsules *	Orlistat 120 mg	Roche (M) S/B
2.	Stablon Coated Tablet	Tianeptine 12.5 mg	Zuellig Pharma S/B
3.	Comtan 200 mg Tablet	Entacapone 200 mg	Novartis Corporation S/B
4.	Innohep Injection 2500* Anti-Xa iu/0.25 ml (pre-filled syringe)	Tinzaparin Sodium	Diethelm (M) S/B
5.	Innohep Injection 3500* Anti-Xa iu/0.35 ml (pre-filled syringe)	Tinzaparin Sodium	Diethelm (M) S/B
6.	Innohep Injection 4500* Anti-Xa iu/0.45 ml (pre-filled syringe)	Tinzaparin Sodium	Diethelm (M) S/B
7.	Innohep Injection 10000* Anti-Xa iu/ml (vial)	Tinzaparin Sodium	Diethelm (M) S/B
8.	Innohep Injection 20000* Anti-Xa iu/ml (vial)	Tinzaparin Sodium	Diethelm (M) S/B
9.	Innohep Injection 20000* Anti-Xa iu/ml (pre-filled syringe)(0.5 ml)	Tinzaparin Sodium	Diethelm (M) S/B
10.	Innohep Injection 20000* Anti-Xa iu/ml (pre-filled syringe)(0.7 ml)	Tinzaparin Sodium	Diethelm (M) S/B
11.	Innohep Injection 20000* Anti-Xa iu/ml (pre-filled syringe)(0.9 ml)	Tinzaparin Sodium	Diethelm (M) S/B
12.	Zenapax 25mg/5 ml Vial*	Daclixumab	Roche (M) S/B
13.	HepatectÒ Solution for Intravenous Use 10 ml	Plasma Protein (human) 100 mg thereof Immunoglobulin > 95% with antibodies to HBs antigen not less than 50 iu/ml	Lazuli S/B
14.	Mabthera 100 mg/10 ml Vial	Rituximab 100 mg	Roche (M) S/B
15.	Mabthera 500 mg/50 ml Vial	Rituximab 500 mg	Roche (M) S/B

\* Conditional approval

### DCA 110 (25/11/99)

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No.	Product	Active Ingredient	Product Registration Holder
1.	Evista 60 mg tablets	Raloxifene Hydrochloride	Eli Lilly (M) Sdn. Bhd.
2.	Micardis 40 mg Tablet	Telmisartan 40.0 mg	Boehringer Ingelheim (M) S/B
3.	Micardis 80 mg Tablet	Telmisartan 80.0 mg	Boehringer Ingelheim (M) S/B
4.	Imigran Nasal Spray 10 mg	Sumatriptan 10 mg	Allen & Hanburys S/B
5.	Imigran Nasal Spray 20 mg	Sumatriptan 20 mg	Allen & Hanburys S/B
6.	Somatuline PR 30 mg Injection	Lanreotide Acetate	Antah Pharma S/B
7.	Vessel Due F Injection	Sulodexide 600 LSU	Antah Pharma S/B
8.	Vessel Due F Capsule	Sulodexide 250 LSU	Antah Pharma S/B
9.	Viramune 200 mg Tablet	Nevirapine Anhydrous 200 mg	Boehringer Ingelheim (M) S/B

#### **DCA 109 (28/10/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Caelyx Concentrate For Infusion	Doxorubicin Hydrochloride	Schering-Plough S/B
2.	Mandol 500 mg Inj.	Cephmandole Naftate	Eli Lilly (M) S/B
3.	Mandol 1 G Inj.	Cephmandole Naftate	Eli Lilly (M) S/B
4.	Divitren Tablet	Estradiol Valerate 2 mg (White and Blue Tablets) Medroxyprogesterone Acetate 20mg (Blue Tablets)	Apex Pharmacy (M) S/B P. Jaya
5.	Pariet Tablet 10 mg	Sodium Rabeprazole	Eisai (M) S/B
6.	Pariet Tablet 20 mg	Sodium Rabeprazole	Eisai (M) S/B
7.	Fareston 60 mg Tablet	Toremifene Citrate 88.5 mg Equivalent to Toremifene 60 mg	Apex Pharmacy Marketing S/B

#### **DCA 108 (30/9/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Xenetix 250 ? 50 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL
2.	Xenetix 250 ? 100 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL

3.	Xenetix 300 ? 50 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL
4.	Xenetix 300 ? 100 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL
5.	Xenetix 350 ? 50 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL
6.	Xenetix 350 ? 100 ml Solution for intravenous injection	lobitridol	Ken-Med S/B, KL
7.	Viracept 250 mg Tablets	Nelfinavir Mesylate 250 mg	Roche (M) S/B
8.	Viracept 50 mg/g Oral Powder	Nelfinavir Mesylate 50 mg/g	Roche (M) S/B
9.	Aggrastat Solution for Infusion	Tirofiban Hydrochloride	Merck Sharp & Dohme (IA) Corp., PJ
10.	Tetramune Vaccine	Haemophilus Influenza type B Diphtheria Toxoid (adsorbed) Tetanus Toxoid (adsorbed) Pertussis Vaccine (adsorbed)	Wyeth (M) S/B
11.	Tevetan 300 mg tablet	Eprosartan Mesylate 367.91 mg	Smithkline Beecham Sdn. Bhd.
12.	Tevetan 400 mg tablet	Eprosartan Mesylate 490.55 mg	Smithkline Beecham Sdn. Bhd.
13.	Lipobay 0.1 mg Tablet	Cerivastatin	Bayer (M) S/B
14.	Lipobay 0.2 mg Tablet	Cerivastatin	Bayer (M) S/B
15.	Lipobay 0.3 mg Tablet	Cerivastatin	Bayer (M) S/B

**DCA 107 (26/8/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Stocrin Capsule 50 mg	Efavirenz 50 mg	Merck Sharp & Dohme, Corp.
2.	Stocrin Capsule 100 mg	Efavirenz 100 mg	Merck Sharp & Dohme, Corp.
3.	Stocrin Capsule 200 mg	Efavirenz 200 mg	Merck Sharp & Dohme, Corp.
4.	Propecia Tablet	Finasteride 1 mg	Merck Sharp & Dohme, (I.A.) Corp.
5.	Unat 2.5 mg Tablet	Torasemide	Roche (Malaysia) S/B
6.	Unat 5 mg Tablet	Torasemide	Roche (Malaysia) S/B
7.	Unat 10 mg Tablet	Torasemide	Roche (Malaysia) S/B

8.	Unat 10 mg Ampoules	Torasemide	Roche (Malaysia) S/B
9.	Pentaglobinâ 50 ml	Human Plasma ) 95% protein 50 mg/ml Immunoglobulin G 38 mg/ml Immunoglobulin M 6 mg/ml Immunoglobulin A 6 mg/ml	Lazuli S/B, P. Jaya
10.	Cefron 1g IV Injection	Cefpirome Sulfate 1191.0 mg equivalent to Cefpirome 1000.0 mg	Agrevo H.S. (Malaysia) S/B
11.	Tablet Plavix	Clopidogrel 75 mg	Sanofi Synthelabo (M) S/B

**DCA 105 (24/6/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Difosfen Tablet 200 Mg	Etidronate Disodium	Zyfas Medical Co., Johor
2.	Statex Suppositories 5 Mg	Morphine Sulphate 5.10 Mg	Kyowa Hakko (M) S/B
3.	Statex Suppositories 10 Mg	Morphine Sulphate 10.20 Mg	Kyowa Hakko (M) S/B
4.	Statex Suppositories 20 Mg	Morphine Sulphate 20.40 Mg	Kyowa Hakko (M) S/B
5.	Statex Suppositories 30 Mg	Morphine Sulphate 30.60 Mg	Kyowa Hakko (M) S/B
6.	Eloxatin 100 Mg Freeze-Dried Powder For Infusion	Oxaliplatin 100 Mg	Sanofi (M) S/B
7.	Eloxatin 50 Mg Freeze-Dried Powder For Infusion	Oxaliplatin 50 Mg	Sanofi (M) S/B
8.	Femoston 2/20 Tablet	Estradiol Hemihydrate micronised 2.06 Mg Estradiol Hemihydrate micronised 2.06 Mg / Dydrogesterone micronised 20.0 Mg	Zuellig Pharma S/B
9.	Femoston 2/10 Tablet	Estradiol Hemihydrate micronised 2.06 Mg Estradiol Hemihydrate micronised 2.06 Mg / Dydrogesterone micronised 10.0 Mg	Zuellig Pharma S/B
10.	Combivir Tablet	Lamivudine 150 Mg Zidovudine 300 Mg	Allen & Hanbury (M) S/B
11.	Driptane 5 Mg	Oxybutynin Hydrochloride	Antah Pharma, Selangor

**DCA 104 (27/5/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Singulair 5 Mg Chewable Tablet	Montelukast Sodium	Merck Sharp & Dohme (I.A.) Corp. Malaysia
2.	Singulair 10 Mg Chewable	Montelukast Sodium	Merck Sharp & Dohme (I.A.)

	Tablet		Corp. Malaysia
3.	Casodex 50 Mg Tablet	Bicalutamide	Zeneca Pharma (m) S/B
4.	Oxistat Cream 17	Oxiconazole Nitrate	Allen & Hanburys Sdn. Bhd. PJ
5.	Hyzaar Tab.	Losartan Potassium 50 Mg Hydrochlorothazide 12.5 Mg	Summit Co. (M) S/B, PJ
6.	Amaryl 1.0 Mg Tablet	Glimepiride	Agrevo HS (Malaysia) S/B, PJ
7.	Amaryl 2.0 Mg Tablet	Glimepiride	Agrevo HS (Malaysia) S/B, PJ
8.	Amaryl 3.0 Mg Tablet	Glimepiride	Agrevo HS (Malaysia) S/B, PJ
9.	Amaryl 4.0 Mg Tablet	Glimepiride	Agrevo HS (Malaysia) S/B, PJ
10.	Amaryl 6.0 Mg Tablet	Glimepiride	Agrevo HS (Malaysia) S/B, PJ
11.	Requip 0.25 Mg Tablet	Ropinirole Hydrochloride 0.285 Mg	Smithkline Beecham S/B
12.	Requip 1 Mg Tablet	Ropinirole Hydrochloride 1.14 Mg	Smithkline Beecham S/B
13.	Requip 2 Mg Tablet	Ropinirole Hydrochloride 2.28 Mg	Smithkline Beecham S/B
14.	Requip 5 Mg Tablet	Ropinirole Hydrochloride 5.70 Mg	Smithkline Beecham S/B
15.	Aprovel Tablet 75 Mg	Irbesartan	Sanofi malaysia S/B
16.	Aprovel Tablet 150 Mg	Irbesartan	Sanofi malaysia S/B
17.	Aprovel Tablet 300 Mg	Irbesartan	Sanofi malaysia S/B
18.	Diastabol 50 Tablet	Miglitol 50 Mg	Sanofi malaysia S/B
19.	Diastabol 100 Tablet	Miglitol 100 Mg	Sanofi malaysia S/B
20.	Exelon Capsule 1.0 Mg	Rivastigmine Hydrogen Tartarate	Novartis Corp. (M) S/B
21.	Exelon Capsule 1.5 Mg	Rivastigmine Hydrogen Tartarate	Novartis Corp. (M) S/B
22.	Exelon Capsule 3.0 Mg	Rivastigmine Hydrogen Tartarate	Novartis Corp. (M) S/B
23.	Exelon Capsule 4.5 Mg	Rivastigmine Hydrogen Tartarate	Novartis Corp. (M) S/B
24.	Exelon Capsule 6.0 Mg	Rivastigmine Hydrogen Tartarate	Novartis Corp. (M) S/B

**DCA 103 (15/4/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Tazocin 2.25 gm injection	Piperacillin Tazobactam	Wyeth (M) S/B

2.	Tazocin 4.5 gm injection	Piperacillin Tazobactam	Wyeth (M) S/B
3.	Ditropan Syrup 5 mg/5 ml	Oxybutynin chloride	Agrevo HS Malaysia
4.	Ditropan Tablet 5 mg	Oxybutynin chloride	Agrevo HS Malaysia
5.	Echovist ? 200	D(+) ? Galactose	Zuellig Pharma S/B

**DCA 102 (25/2/99)**

No.	Product	Active Ingredient	Product Registration Holder
1.	Topamax 25mg	Topiramate 25mg	Johnson & Johnson Sdn. Bhd.
2.	Topamax 50mg	Topiramate 50mg	Johnson & Johnson Sdn. Bhd.
3.	Topamax 100mg	Topiramate 100mg	Johnson & Johnson Sdn. Bhd.
4.	Topamax 200mg	Topiramate 200mg	Johnson & Johnson Sdn. Bhd.
5.	Prograf Capsule 1mg	Tacrolimus 1mg	Johnson & Johnson Sdn. Bhd.
6.	Prograf Capsule 5mg	Tacrolimus 5mg	Johnson & Johnson Sdn. Bhd.
7.	Prograf Concentrate For Infusion	Tacrolimus 5mg/ml	Johnson & Johnson Sdn. Bhd.
8.	Fludara Injection	Fludarabine Phosphate	Zeullig Pharma Sdn. Bhd.
9.	Simulect Lyophilisate For Injection 20mg/vial	Basiliximabum 20mg	Novartis Corporation (M) Sdn. Bhd.
10.	Aricept Tablet 5mg	Donepezil Hydrochloride	Eisai (M) Sdn. Bhd.
11.	Aricept Tablet 10mg	Donepezil Hydrochloride	Eisai (M) Sdn. Bhd.
12.	BIO-Enhance Natopherol 100 IU	d-alpha Tocopherol 100 IU (67.5mg)	Abbot Laboratories (M) Sdn. Bhd.
13.	BIO-Enhance Natopherol 250 IU	d-alpha Tocopherol 250 IU (167.5mg)	Abbot Laboratories (M) Sdn. Bhd.