



(Escitalopram oxalate)

Selangor

2. 2.1 **HERCEPTIN VIAL 150MG  
POWDER FOR CONCENTRATE**

**HERCEPTIN VIAL 440MG  
POWDER FOR CONCENTRATE**

(Trastuzumab)

Metastatic Breast Cancer (mBC):

Herceptin is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2:

- in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer.

Roche (Malaysia) Sdn Bhd  
The Selangor Dredging  
142 Jalan Ampang  
50450 Kuala Lumpur

**DCA 206 (26 Jun 2008)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1. 1.1	<b>GLIVEC 500MG CAPSULES</b>  <b>GLIVEC 100MG CAPSULES</b>  <b>GLIVEC 100MG TABLETS</b>  <b>GLIVEC 400MG TABLETS</b>  (Imatinib mesylate)	<p><u>Penilaian Penuh:</u></p> <p>Glivec is indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutational status unknown.</li> </ul> <p>The effectiveness of Glivec is based on haematological response rates in SM.</p> <p><u>Penilaian Verifikasi:</u></p> <p>Glivec is indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>Adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy.</li> <li>Adult patients with relapsed or refractory Ph+ ALL as monotherapy.</li> <li>Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) with FIP1L1-PDGFR<math>\alpha</math> rearrangement.</li> <li>Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).</li> </ul>	Novartis Corporation (M) Sdn Bhd Level 15 CREST 3 Two Square No 2 Jalan 19/1 46300 Petaling Jaya Selangor
2. 2.1	<b>AVASTIN 25MG/ML</b>  <b>INJECTION</b>	<p><u>Metastatic Breast Cancer (mBC):</u></p> <p>Avastin in combination with</p>	Roche (M) Sdn. Bhd. 14 <sup>th</sup> Floor, West Block Wisma Selangor Dredging

(Bevacizumab)

paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer. 142 Jalan Ampang 50450 Kuala Lumpur.

Advanced, metastatic or recurrent Non Small Cell Lung Cancer (NSCLC):

- Avastin, in addition to platinum-based chemotherapy, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer.

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**DCA 205 (29 Mei 2008)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1. 1.1	<b>HUMIRA SOLUTION FOR INJECTION</b>  (Adalimumab)	<u>Crohn's Disease</u> Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adults patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab.	Abbot Laboratories (M) Sdn Bhd No 22 Jalan Pemaju U1/15 Section U1 Industrial Park 40150 Shah Alam Selangor
2. 2.1	<b>SPRYCEL 20MG TABLET</b>  <b>SPRYCEL 50MG TABLET</b>  <b>SPRYCEL 70MG TABLET</b>  (dasatinib)	<u>Dosage an Administration</u> The recommended starting dosage of Sprycel (dasatinib) for chronic phase CML is 100mg administered orally once daily(QD), either in the morning or in the evening. The recommended starting dosage of Sprycel for accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL is 140mg/day administered orally in two divided doses (70mg twice daily[BID]), one in the morning and one in the evening. Tablets should not be crushed or cut, they should be swallowed whole. Sprycel can be taken with or without meal.  <u>Dose Escalation</u> In clinical studies of adult CML and Ph+ ALL patients, dose escalation to 140mg once daily (chronic phase CML) or 100mg twice daily (advanced phase CML and Ph+ ALL) was allowed in patients who did not achieve a hematologic or cytogenetic response at the recommended starting dosage.  <u>Dose Adjustment for Adverse Reaction</u> Myelosuppression In clinical studies, myelosuppression was managed by dose interruption,	Bristol-Myers Squibb (M) Sdn Bhd 17 <sup>th</sup> Floor Menara Lien Hoe 8 Persiaran Tropicana 47410 Petaling Jaya Selangor

dose reduction, or discontinuation of study therapy. Hematopoietic growth factor has been used in patients with resistant myelosuppression. Guidelines for dose modifications are summarized in Table 1.

Chronic Phase CML (starting dose 100mg once daily)	ANC* < 0.5 x 10 <sup>9</sup> /L or Platelets < 50 x 10 <sup>9</sup> /L	1. Stop SPRYCEL until ANC ≥ 1.0 x 10 <sup>9</sup> /L and the platelets ≥ 50 x 10 <sup>9</sup> /L 2. Resume treatment with SPRYCEL at the original starting dose if recovery occurs in ≤ 7 days. 3. If platelets < 25 x 10 <sup>9</sup> /L or recurrence of ANC < 0.5 x 10 <sup>9</sup> /L for > 7 days, repeat step 1 and resume SPRYCEL at a reduced dose of 80mg once daily (second episode) or discontinue (third episode)
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**DCA 204 (29 April 2008)**

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	BYETTA INJECTION 5 MCG BYETTA INJECTION 10 MCG (Exenatide)	➤ Byetta is indicated as adjunctive therapy to improve glyceamic control in patients with type 2 diabetes mellitus who are taking thiazolidinedione or a combination of metformin and thiazolidinedione, but have not achieved adequate glyceamic control.	Eli Lilly (M) Sdn Bhd Unit 18.1 Level 18 CP Tower No 11 Jalan 16/11 Pusat Dagang Seksyen 16 46350 Petaling Jaya, Selangor
2.	2.1	DYSPORE 500U/VIAL, POWDER FOR INJECTION  (Clostridium Botulinum Type A toxin-haemagglutinin complex)	➤ Dysport® is indicated for focal spasticity, including the treatment of: - Arm symptoms associated with focal spasticity in conjunction with physiotherapy.	Emerging pharma Sdn Bhd Phileo Damansara II 3A03 Block B No 15 Jalan 16/11 46350 Petaling Jaya Selangor
3.	3.1 3.2 3.3	SINGULAIR CHEWABLE TABLET 5MG  SINGULAIR 4MG CHEWABLE TABLET	➤ Singulair is indicated in adults and paediatric patients <u>2 years of age and older</u> for the relief of daytime and night time symptoms of seasonal allergic rhinitis.	Merck Sharp & Dohme (IA) Corp T-2-9 Jalan 33 No 3 (Lot 33) Jalan Semangat

	SINGULAIR GRANULES  (montelukast sodium)	4MG  ORAL		Seksyen 13 46100 Petaling Jaya, Selangor
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**DCA 202 (28 Februari 2008)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 CRESTOR 5 MG TABLET 1.2 CRESTOR 10 MG TABLET 1.2 CRESTOR 20 MG TABLET  (Rosuvastatin calcium)	Crestor is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adults patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.	AstraZeneca Sdn Bhd Wisma Prima 17 Jalan Sri Semantan Satu Damansara Heights 50490 Kuala Lumpur
2.	2.1 KEPPRA 250MG FILM COATED TABLET 2.2 KEPPRA 500MG FILM COATED TABLET 2.3 KEPPRA 1000MG FILM COATED TABLET  KEPPRA ORAL SOLUTION 100 MG/ML  (Levetiracetam)	Keppra is indicated as monotherapy in the treatment of partial seizure with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy.  Keppra is indicated as adjunctive therapy: ➤ In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME). ➤ In the treatment of primary generalized tonic-clonic seizures (PGTCS) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.	UCB Pharma Asia Pacific Sdn Bhd Level 2 & 3 Block B Plaza Damansara No 45 Medan Setia 1 Bukit Damansara 50490 Kuala Lumpur

**DCA 201 (31 Januari 2008)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 PLAVIX TABLET 75MG  (Clopidogrel hydrogen sulphate)	➤ Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention.	Sanofi-Aventis (M) Sdn Bhd 8th Floor, PNB Damansara No. 19, Lorong Dungun Damansara Heights 50490 Kuala Lumpur
2.	2.1 CELEBREX CAPSULE 100MG 2.2 CELEBREX CAPSULE 200MG  (Celecoxib)	➤ Relief of signs and symptoms of ankylosing spondylitis.	Pfizer (Malaysia) Sdn Bhd Level 3&4, Bangunan Palm Grove No. 14, Jalan Glenmarie Persiaran Kenjaya, Section U1 40150 Shah Alam Selangor