Products Approved For Additional Indication (DCA 245 – 25 OCTOBER 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	HERCEPTIN VIAL 440 MG POWDER FOR CONCENTRATE (Trastuzumab 440 mg/vial)	***Early Breast Cancer (EBC)*** ***Herceptin is indicated for the treatment of patients with HER2 positive early breast cancer*** • ***following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).*** • ***following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel.*** • ***in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.***	**ROCHE (M) SDN BHD, THE INTERMARK, 182, JALAN TUN RAZAK, 50400 KUALA LUMPUR.**
	1.2	HERCEPTIN VIAL 150 MG POWDER FOR CONCENTRATE (Trastuzumab 150 mg/vial)		
	1.3	HERCEPTIN VIAL 150 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION (Trastuzumab 150 mg/vial)		

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Products Approved For Additional Indication (DCA 2 – 27 Januari 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**HUMIRA SOLUTION FOR INJECTION** (Adalimumab 40 mg/0.8 ml)	➢ *Polyarticular uvenile Idiopathic Arthritis* *umira in combination with methotrexate is indicated for the treatment of active polyarticular uvenile idiopathic arthritis, in adolescents aged 13 to 17 years who have had an inade uate response to one or more disease modifying anti-rheumatic drugs (MA S). umira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.*	ABBOTT LABORATORIES (M) SDN BHD, NO. 22, JALAN PEMAJU U1/15, SECTION U1, HICOM-GLENMARIE INDUSTRIAL PARK, 40150 SHAH ALAM, SELANGOR
2.0	2.1	**OLAIR 150MG PO DER AND SOLVENT FOR SOLUTION FOR INJECTION** (Omalizumab, 150 mg/vial)	• *<u>Children (to 12 years of age)</u>* *Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and fre uent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta 2-agonist.*	NOVARTIS CORPORATION (M) SDN BHD LEVEL 15, CREST, 3 TWO SQUARE NO. 2, JALAN 19/1, 46300 PETALING JAYA, SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.0	3.1	**ALDARA CREAM 5%** (Imiquimod 5% w/w)	➢ *Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults.* ➢ *Treatment of biopsy-confirmed, primary superficial basal cell carcinoma (s CC) in immunocompetent adults, with a maximum tumour diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured.* - *The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of Aldara Cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.*	iNova Pharmaceuticals (Singapore) Pte Ltd (Incorporated In Singapore) Malaysia Branch, Level 5, Wisma Samudra, No 1, Jalan Kontraktor U1/14, Hicom-Glenmarie Industrial Park 40150 Shah Alam Selangor
4.0	4.1	**PRADA A 110 MG, HARD CAPSULE** (Dabigatran etexilate mesilate 126.83 mg equivalent to dabigatran free base 110 mg)	*eduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.*	Boehringer Ingelheim (Malaysia) Sdn Bhd Suite 15-5, level 15 Wisma UOA Damansara II No. 6 Jalan Changkat Semantan Damansara Heights 10490 Kuala Lumpur
5.0	5.1 5.2	**TAMIFLU ORAL SUSPENSION 12MG/ML** (Oseltamivir phosphate 12mg/mL) **TAMIFLU CAPSULE 0MG** (Oseltamivir phosphate 39.40mg equivalent to oseltamivir 30.0mg)	*Tamiflu is indicated for the treatment of influen a in children to 12 months of age during a pandemic influen a outbreak.*	Roche (M) Sdn. Bhd. 14th. Floor, West Block Wisma Selangor Dredging, 142, Jalan Ampang 50450 Kuala Lumpur

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
	5.3	**TAMIFLU CAPSULE 45MG** (Oseltamivir phosphate 59.10mg equivalent to oseltamivir 45.0mg)		
	5.4	**TAMIFLU CAPSULES 75MG** (Oseltamivir phosphate 98.5mg equivalent to oseltamivir 75.0mg)		
	5.5	**TAMIFLU CAPSULE 75MG** (Oseltamivir phosphate 98.5mg equivalent to oseltamivir 75.0mg)		

Products Approved For Additional Indication (DCA 2 7 – 17 Mac 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**ZELDO CAPSULE 20MG** (ziprasidone hydrochloride monohydrate 22.7mg equivalent to 20mg ziprasidone)	➢ *ipolar I isorder* • *iprasidone is indicated as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder. fficacy was established in two 3-week monotherapy studies in adult patients.* • *iprasidone is indicated as an ad unct to lithium or valproate for the maintenance treatment of bipolar I disorder. fficacy was established in a maintenance trial in adult patients. The efficacy of iprasidone as monotherapy for the maintenance treatment of bipolar I disorder has not been systematically evaluated in controlled clinical trials.* *P S G* ➢ *ipolar I isorder* • *Acute Treatment of Manic or Mixed pisodes* - *The recommended initial dose is 0 mg twice daily, to be taken with food. aily dosage may subse uently be ad usted on the basis of individual clinical status up to a maximum of 0 mg twice daily. If indicated, the maximum recommended dose may be reached as early as ay 3 of treatment.* • *Maintenance Treatment (as an ad unct to lithium or valproate)* - *Continue treatment at the same dose on which the patient was initially stabilised, within the range of 0 mg - 0 mg twice daily with food. Patients should be periodically reassessed to determine the need for maintenance treatment.*	Pfizer (M) Sdn. Bhd. Level 3 & 4 Bangunan Palm Grove No. 14 Jalan Glenmarie Section U1 40150 Shah Alam Selangor
	1.2	**ZELDO CAPSULE 40MG** (ziprasidone hydrochloride monohydrate 45.3mg equivalent to 40mg ziprasidone)		
	1.3	**ZELDO CAPSULE 0MG** (ziprasidone hydrochloride monohydrate 68.0mg equivalent to 60mg ziprasidone)		
	1.4	**ZELDO CAPSULE 80MG** (ziprasidone hydrochloride		

		monohydrate 90.6mg equivalent to 80mg ziprasidone)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1	**NOVORAPID FLE PEN 100 IU/ML** (INSULIN ASPART)	➢ *Treatment of diabetes mellitus in adults and adolescents and children aged 2 to 17 years.*	Novo Nordisk Pharma (Malaysia) Sdn. Bhd. A-9-2 Level 9, Tower A, Menara UOA Bangsar, No. 5, Jalan Bangsar Utama 1 59000 Kuala Lumpur.
	2.2	**NOVORAPID PENFILL 100IU/ML** (INSULIN ASPART)		

Products Approved For Additional Indication (DCA 2 8 – 1 Mac 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**B ETTA INJECTION 5MCG** (Exenatide 250 mcg/1ml) **B ETTA INJECTION 10MCG** (Exenatide 250 mcg/1ml)	• *TTA is indicated as an ad unct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.* • *Important imitations of se* *TTA is not a substitute for insulin. TTA should not be used in patients with type I diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.* • *The concurrent use of TTA with insulin has not been studied and cannot be recommended.* • *ased on postmarketing data TTA has been associated with acute pancreatitis, including fatal and non-fatal haemorrhagic or necrotising pancreatitis. TTA has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using TTA. ther antidiabetic therapies should be considered in patients with a history of pancreatitis.* *Posology* - *TTA is recommended as a monotherapy in patients with type 2 diabetes as an ad unct to diet and exercise.*	Eli Lilly (Malaysia) Sdn. Bhd. Unit 18.1, Level 18, CP Tower, No. 11, Jalan 16/11, Pusat Dagang Seksyen 16, 46350 Petaling Jaya, Selangor
	1.2			

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1	**QLAIRA FILM-COATED TABLET** (Each calendar pack (28 film-coated tablets) contains in the following order: • 2 dark yellow tablets containing 3mg estradiol valerate • 5 medium red tablets containing 2mg estradiol valerate and 2mg dienogest • 17 light yellow tablets each containing 2mg estradiol valerate and 3mg dienogest • 2 dark red tablets each containing 1mg estradiol valerate • 2 white placebo tablets)	➢ *Treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraception.*	Bayer Co. (Malaysia) Sdn. Bhd. T1-14 Jaya 33 No.3, Jalan Semangat, Seksyen 13 46200 Petaling Jaya Selangor

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.0	3.1	**TENVIR FILM-COATED TABLET** (Tenofovir disoproxil fumarate 300mg equivalent to tenofovir disoproxil 245mg)	*Chronic hepatitis* *T NVI is indicated for the treatment of chronic hepatitis in adults.* *The following points should be considered when initiating therapy with T NVI for the treatment of V infection:* • *This indication is based primarily on data from treatment of sub ects who were nucleoside-treatment-na ve and a smaller number of sub ects who had previously received lamivudine or adefovir dipivoxil. Sub ects were adults with eAg-positive and eAg-negative chronic hepatitis with compensated liver disease.* • *T NVI was evaluated in a limited number of sub ects with chronic hepatitis and decompensated liver disease.* • *The numbers of sub ects in clinical trials who had lamivudine- or adefovir associated substitutions at baseline were too small to reach conclusions of efficacy* *Posology* *ecommended ose in Adults* *or the treatment of IV-1 or chronic hepatitis : The dose is one 300 mg T NVI tablet once daily taken orally, without regard to food.* *In the treatment of chronic hepatitis , the optimal duration of treatment is unknown.* *ose Ad ustment for enal Impairment in Adults* *Significantly increased drug exposures occurred when T NVI was administered to sub ects with moderate to severe renal impairment. Therefore, the dosing interval of T NVI should be ad usted in patients with baseline creatinine clearance 50 m /min using the recommendations in Table 1. These dosing interval recommendations are based on modelling of single-dose pharmacokinetic data in non- IV and non- V infected sub ects with varying degrees of renal impairment, including end-stage renal disease re uiring haemodialysis. The safety and effectiveness of these dosing interval ad ustment recommendations have not been clinically evaluated in patients with moderate or severe renal impairment, therefore clinical response to treatment and renal function should be closely monitored in these patients.* *No dose ad ustment is necessary for patients with mild renal impairment (creatinine clearance*	Medispec (M) Sdn. Bhd. No. 55, Lorong Sempadan 2, 11400 Ayer Itam, Pulau Pinang.

50 0 m /min). outine monitoring of calculated creatinine clearance and serum phosphorus should be performed in patients with mild renal impairment.

Table 1 osage Ad ustment for Patients with Altered Creatinine Clearance

	Creatinine Clearance (m /min) [a]			*aemodialysis Patients*
	50	*30-*	*10-2*	
ecommended 300 mg osing Interval	*very 2 hours*	*very hours*	*very 72 to hours*	*very 7 days or after a total of approximately 12 hours of dialysis* [b]

a. Calculated using ideal (lean) body weight.

b. Generally once weekly assuming three haemodialysis sessions a week of approximately hour duration.
T NVI should be administered following completion of dialysis.

The pharmacokinetics of tenofovir have not been evaluated in non-haemodialysis patients with creatinine clearance 10 m /min therefore, no dosing recommendation is available for these patients.

- *No data are available to make dose recommendations in paediatric patients 12 years of age and older with renal impairment.*

Products Approved For Additional Indication (DCA 2_9 – 21 April 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**D SPORT 500U/VIAL, PO DER FOR INJ** (Clostridium botulinum toxin type A 500 units/vial)	➢ *ysport is also indicated for the following treatments:* - *Moderate to severe glabellar lines in adults.* - *Axillary hiperhydrosis in adults.*	Emerging Pharma Sdn Bhd Phileo Damansara II 3A03 Block B, 15 Jalan 16/11 46350 Petaling Jaya Selangor

Products Approved For Additional Indication (DCA 240 – 2 Mei 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**ACTEMRA 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION** [Tocilizumab (interleukin-6 receptor inhibitor) 20mg/ ml]	*Tocili umab has been shown to reduce the rate of progression of oint damage as measured by X- ay and to improve physical function when given in combination with methotrexate (MTX).*	Roche (M) Sdn Bhd The Intermark, Jalan Ampang 50450 Kuala Lumpur
2.	2.1	**FOSRENOL CHE ABLE TABLETS 250MG** (Lanthanum carbonate hydrate 477mg equivalent to lanthanum 250mg)	*osrenol is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.*	IDS Services (Malaysia) Sdn Bhd Lot 6, Persiaran Perusahaan Sec 23, Kawasan Perusahaan Shah Alam 40300 Shah Alam Selangor
	2.2	**FOSRENOL CHE ABLE TABLETS 500MG** (Lanthanum carbonate hydrate 954mg equivalent to lanthanum 500mg)		
	2.3	**FOSRENOL CHE ABLE TABLETS 750MG** (Lanthanum carbonate hydrate 1431mg equivalent to lanthanum 750mg)		
	2.4	**FOSRENOL CHE ABLE TABLETS 1000MG** (Lanthanum carbonate hydrate 1908mg equivalent to lanthanum 1000mg)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.	3.1	**SEROQUEL R E TENDED RELEASE TABLET 50MG** (Quetiapine fumarate 57.56mg equivalent to 50mg quetiapine free base)	➢ *Ma or depressive disorder* - *Treatment of recurrent ma or depressive disorder (M) in patients who are intolerant of, or who have an inade uate response to alternative therapies.* *Posology* *<u>Adults:</u>* *ecurrent ma or depressive disorder* *When treating recurrent M in patients who are intolerant of, or who have an inade uate response to alternative therapies, treatment should be initiated either by the treating psychiatrist or by the general practitioner after consultation with the psychiatrist.* *Sero uel X should be administered once daily in the evening.* *Initial dosing should begin at 50 mg on ay 1 and 2, increased to 150 mg on ay 3 and . The usual effective dose in M is 150 mg. urther ad ustments can be made upwards or downwards within the recommended dose range of 50 mg to 300 mg depending upon the clinical response and tolerability of the patient.* *Patients who have not responded to Sero uel X after weeks treatment for M should have treatment re-evaluated.* *or maintenance therapy in M in patients who have responded to acute treatment, the effective dose during initial treatment should be continued. It is generally recommended that responding patients be continued beyond the acute response, but at the lowest possible dose needed to maintain remission. The dose can be ad usted within the recommended dose range depending upon the clinical response and tolerability of the patient. Patients should be periodically reassessed to determine the need for maintenance treatment.* *ong-term safety of Sero uel X in M has not been systematically evaluated (52 weeks). Thus, the physician who elects to use Sero uel X in the treatment of M should use Sero uel X for the shortest time that is clinically indicated. When lengthier treatment is indicated, the physician must periodically re-evaluate the long-term usefulness of the drug for the individual patient keeping in mind the long-term risks.*	AstraZeneca Sdn Bhd Level 12, Surian Tower 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya Selangor
	3.2	**SEROQUEL R E TENDED RELEASE TABLET 200MG** (Quetiapine fumarate 230.26mg equivalent to 200mg quetiapine free base)		
	3.3	**SEROQUEL R E TENDED RELEASE TABLET 00MG** (Quetiapine fumarate 345.38mg equivalent to 300mg quetiapine free base)		
	3.4	**SEROQUEL R E TENDED RELEASE TABLET 400MG** (Quetiapine fumarate 460.50mg equivalent to 400mg quetiapine free base)		

			Iderly: *In elderly patients with M , initial dosing should begin at 50 mg on ays 1-3, the dose can be increased to 100 mg on ay , 150 mg on ay and* then up to 300 mg depending on clinical response and tolerability.	

Products Approved For Additional Indication (DCA 241 – 2 Jun 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**SUTENT 12.5MG CAPSULE** (Sunitinib malate16.7mg equivalent to 12.5mg sunitinib)	- *Pancreatic neuroendocrine tumours (pN T)* *S T NT is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.* *xperience with S T NT as first-line treatment is limited.* *Posology* *ecommended ose* *or Pancreatic Neuroendocrine Tumour (pN T), the recommended dose of sunitinib is 37.5 mg taken orally once daily without a scheduled rest period.* *ose Modifications* *or pN T, dose modification in 12.5 mg steps may be applied based on individual safety and tolerability. The maximum dose administered in the Phase 3 pN T study was 50 mg daily.* *C P3A inhibition / induction.* *Co-administration of sunitinib with strong C P3A inducers such as rifampin, should be avoided. If this is not possible, the dose of sunitinib may need to be increased in 12.5 mg steps (up to 7.5 mg per day for Gastrointestinal Stromal Tumour and Advanced enal Cell Carcinoma or 2.5 mg per day for pN T), based on careful monitoring of tolerability.* *Co-administration of sunitinib with strong C P3A inhibitors, such as ketocona ole, should be avoided. If this is not possible, the dose of sunitinib may need to be reduced to a minimum of 37.5 mg daily for Gastrointestinal Stromal Tumour and Advanced enal Cell Carcinoma or 25 mg daily for pN T, based on careful monitoring of tolerability.*	**Pfizer (Malaysia) Sdn. Bhd.** **Level 4, Bangunan Palm Grove,** **No. 14 Jalan Glenmarie (Persiaran Ker aya)** **Section U1,** **40150 Shah Alam,** **Selangor**
	1.2	**SUTENT 25MG CAPSULE** (Sunitinib malate **.4**mg equivalent to 25mg sunitinib)		
	1.3	**SUTENT 50MG CAPSULE** (Sunitinib malate 66.8mg equivalent to 50mg sunitinib)		

DCA 242 – 28 Julai 2011)

		(ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**Nasacort Aq Nasal Spray** (Triamcinolone Acetonide 55MCG/ actuation)	➢ *Nasacort AQ Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older* *Posology:* *Children 2 to 5 years of age: The recommended and maximum dose is 110mcg per day given as one spray in each nostril once daily.* *Nasacort AQ Nasal Spray is not recommended for children under 2 years of age.*	**Sanofi-Aventis (Malaysia) Sdn. Bhd.** **8th Floor, PNB Damansara** **No. 19, Lorong Dungun** **Damansara Heights** **50490 Kuala Lumpur**
2.	2.1	**Plavix Tablet 75mg** (Clopidogrel hydrogen sulphate 97.875MG equivalent to 75MG clopidogrel base)	➢ *Prevention of atherothrombotic and thromboembolic events in atrial fibrillation* *In adult patients with atrial fibrillation who have at least one risk factor for vascular events, who are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.* *Posology:* *In patients with atrial fibrillation, clopidogrel should be given as a single daily dose of 75 mg.* *ASA (75-100mg daily) should be initiated and continued in combination with clopidogrel.*	**Sanofi-Aventis (Malaysia) Sdn Bhd** **8th Floor, PNB Damansara,** **No. 19, Lorong Dungun** **Damansara Heights** **50490 Kuala Lumpur**
3.	3.1 3.2	**MABTHERA 100MG/10ML VIALS** (Rituximab 100MG/10ML) **MABTHERA 500MG/50ML VIALS** (Rituximab 500MG/50ML)	➢ posology for Mabthera as maintenance therapy in previously untreated follicular lymphoma patients responding to induction therapy. *<u>Maintenance treatment</u>* *Previously untreated patients after response to induction treatment may receive maintenance therapy with Mabthera given at 375mg/m2 body surface*	**Roche (M) Sdn Bhd,** **Level 58, The Intermark,** **182, Jalan Tun Razak** **50400 Kuala Lumpur.**

		(Rituximab 10MG/ML)	*area once every 2 months (starting 2 months after the last dose of induction therapy) until disease progression or for a maximum period of two years (12 infusions).*	
	3.4	**MABTHERA 100MG/10ML VIALS** (Rituximab 100MG)		
	3.5	**MABTHERA 500MG/50ML VIALS** (Rituximab 500MG)		
4.	4.1	**Gamunex, Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified** (Human Immunoglobulin Proteins 0.1G)	➢ Gamunex is an immune globulin intravenous (human) 10% liquid indicated for the treatment of: <u>Primary Humoral Immunodeficiency (PI)</u> *Gamunex is indicated as replacement therapy of primary humoral immunodeficiency. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.*	**SkyQuest Enterprise No. 52, Jalan SS 22/25, Damansara Jaya, 47400 Petaling Jaya, Selangor.**

Products Approved For Additional Indication (DCA 243 – 25 Ogos 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**BARACLUDE TABLET 0.5 MG** (Entecavir 0.5mg)	➢ *BARACLUDE (entecavir) is indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.* *The following points should be considered when initiating therapy with BARACLUDE:* • *This indication is based on histologic, virologic, biochemical, and serologic responses in nucleoside-treatment-naive and lamivudine-resistant adult patients with HBeAg-positive or HBeAg-negative chronic HBV infection with compensated liver disease* • *Virologic, biochemical, serologic, and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease.* • *Virologic, biochemical, serologic, and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.* *Posology* *Decompensated Liver Disease* *The recommended dose for patients with decompensated liver disease is 1 mg once daily, which must be taken on an empty stomach (empty means at least 2 hours before and at least 2 hours after a meal).* *Special Populations* *Patients with renal impairment* *Entecavir is predominantly eliminated by the kidney. The clearance of entecavir decreases with impaired (decreasing) creatinine clearance.* *Dosage adjustment of BARACLUDE is recommended for patients who have a creatinine clearance <50 mL/min, including those on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD), as shown in Table 1.*	**DKSH Malaysia Sdn Bhd 74, Jalan Universiti, 46200, Petaling Jaya, Selangor**

Table 1: Recommended Dosage of BARACLUDE in Patients with Renal Impairment[a]

Creatinine Clearance (mL/min)	Usual Dose (0.5 mg once daily)	Lamivudine-Refractory or Decompensated Liver Disease (1 mg once daily)
30 – <50	0.5 mg every 48 hours	0.5 mg once daily OR 1 mg every 48 hours
10 – <30	0.5 mg every 72 hours	1 mg every 72 hours
<10	0.5 mg every 5-7 days	1 mg every 5-7 days
Haemodialysis[b] or CAPD	0.5 mg every 5-7 days	1 mg every 5-7 days

[a] Do not split tablets.
[b] On haemodialysis days, administer BARACLUDE after haemodialysis.
CAPD=continuous ambulatory peritoneal dialysis.

2. 2.1 **NAROPIN 2MG/ML-20ML POLYAMP** (Ropivacaine HCL 2mg/ml)

Acute pain relief (peri- and postoperative) in children:
- *Caudal epidural block in infants (>30 days old) and children up to and including 12 years.*
- *Continuous epidural infusion in infants (>30 days old) and children up to and including 12 years.*

Posology

Children (>30 days old and up to and including 12 years)

	Strength mg/mL	*Volume mL/kg*	*Dose mg/kg*
ACUTE PAIN MANAGEMENT (peri- and postoperative)			
Single Caudal Epidural Block in children >30 days old and up to 12	*2 mg/mL*	*1 mL/kg*	*2 mg/kg*

ASTRAZENECA Sdn. Bhd.
Level 12, Surian Tower,
1 Jalan PJU 7/3,
Mutiara Damansara
47810, Petaling Jaya,
Selangor

years *Blocks below T12, in children with a body weight up to 25 kg*			
Continuous Epidural Infusion *In children with a body weight up to 25 kg*			
>30 days old and up to 6 months *Bolus dose[a]* *Infusion up to 72 hours*	*2 mg/mL* *2 mg/mL*	*0.5–1 mL/kg* *0.1 mL/kg/h*	*1–2 mg/kg* *0.2 mg/kg/h*
6 up to 12 months *Bolus dose[a]* *Infusion up to 72 hours*	*2 mg/mL* *2 mg/mL*	*0.5–1 mL/kg* *0.2 mL/kg/h*	*1–2 mg/kg* *0.4 mg/kg/h*
1 to 12 years *Bolus dose[b]* *Infusion up to 72 hours*	*2 mg/mL* *2 mg/mL*	*1 mL/kg* *0.2 mL/kg/h*	*2 mg/kg* *0.4 mg/kg/h*

[a] *Doses in the low end of the dose interval are recommended for thoracic epidural blocks while doses in the high end are recommended for lumbar or caudal epidural blocks.*

[b] *Recommended for lumbar epidural blocks.*

The doses in the table should be regarded as recommendations when used in children.

Individual variations occur. For overweight children a gradual reduction of the dosage, based on the ideal body weight, is often necessary. The volume for single caudal epidural block and the volume for epidural bolus doses should not exceed 25 mL in any patient.

Method of Administration

To prevent inadvertent intravascular injections, great caution should be

			observed. Careful aspiration is recommended before and during injection of the total dose. The patient's vital functions should be carefully monitored during the injection. Should toxic signs appear, the injection should be immediately stopped. *When administering the calculated dose, fractionation of the total dose is always recommended.* *A single caudal epidural injection of ropivacaine 2 mg/ml produces adequate postoperative analgesia below T12 in the majority of patients when a dose of 2 mg/kg is used in a volume of 1 ml/kg. The volume of the caudal epidural injection may be adjusted to control the spread of the sensory block. Doses up to 3 mg/kg of a concentration of ropivacaine 3 mg/ml have been used safely in children older than 4 years.* *For children with a body weight over 25 kg there is limited experience of caudal blocks.* *The use of ropivacaine in premature children has not been documented.*	
3.	3.1	**LUCENTIS 10MG/ML SOLUTION FOR INJECTION** (Ranibizumab 10 mg/ml)	➢ *Lucentis is indicated for:* - *the treatment of visual impairment due to diabetic macular oedema (DME).* - *the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (RVO).*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** **LEVEL 15, CREST,** **3 TWO SQUARE,** **NO.2, JALAN 19/1** **46300 PETALING JAYA, SELANGOR**.

Products Approved For Additional Indication (DCA 244 – 26 SEPTEMBER 2011)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	**PLETAAL 50MG TABLETS** (**Cilostazol 50mg**)	• **Prevention of recurrence of cerebral infarction (excluding cardiogenic cerebral embolism)** • **<Precaution> The effects of Pletaal on cerebral infarction have not been studied in patients with asymptomatic cerebral infarction.**	**INVIDA (SINGAPORE) PTE. LTD. LEVEL 2, NO. 10, JALAN BERSATU 13/4, 46200 PETALING JAYA SELANGOR**
	1.2	**PLETAAL 100MG TABLETS** (**Cilostazol 100mg**)		
2.	2.1	**ACTEMRA 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION (Tocilizumab 20 mg/ml)**	• ***Systemic Juvenile Idiopathic Arthritis (sJIA)*** **Tocilizumab is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.**	**ROCHE (M) SDN BHD, THE INTERMARK, 182, JALAN TUN RAZAK, 50400 KUALA LUMPUR.**
3.	3.1	**BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION (Clostridium Botulinum Toxin Type A 100 units/vial)**	• **Botox is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).**	**ALLERGAN MALAYSIA SDN. BHD. G.07, GROUND FLOOR WISMA ACADEMY NO. 4A, JALAN 19/1 46300 PETALING JAYA.**