Products Approved For Additional Indication (DCA 235 – 23 Disember 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**Cutivate Cream 0.05% w/w** (Fluticasone propionate 0.05% w/w)	➢ *Cutivate Cream is indicated for <u>children aged 3 months to less than 1 year</u> for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses such as:* - *Eczema including atopic, infantile, and discoid eczemas;* - *Prurigo nodularis;* - *Psoriasis (excluding widespread plaque psoriasis);* - *Neurodermatoses including lichen simplex;* - *Lichen planus;* - *Seborrhoeic dermatitis;* - *Contact sensitivity reactions;* - *Discoid lupus erythematosus;* - *An adjunct to systemic steroid therapy in generalised erythroderma;* ➢ *The safety and efficacy of drug use for longer than 4 weeks in this population have not been established. The safety and efficacy of CUTIVATE Cream in paediatric patients below 3 months of age have not been established.* *<u>POSOLOGY</u>* *For adults and children aged 3 months and over, apply a thin film of Cutivate Cream to the affected skin areas once or twice daily.*	GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD. 8TH FLOOR, MENARA LIEN HOE NO.8, PERSIARAN TROPICANA 47410 PETALING JAYA SELANGOR

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1 2.2 2.3 2.4	**Seroquel Tablet 25mg** (Quetiapine Fumarate 28.78mg equivalent to 25mg quetiapine free base) **Seroquel Tablet 100mg** (Quetiapine Fumarate 115.13mg equivalent to 100mg quetiapine free base) **Seroquel Tablet 200mg** (Quetiapine Fumarate 230.26mg equivalent to 200mg quetiapine free base) **Seroquel Tablet 300mg** (Quetiapine Fumarate 345.37mg equivalent to 300mg quetiapine free base)	*To extend the usage to paediatrics for these indications:* ❖ *Treatment of schizophrenia.* *The antipsychotic efficacy of Seroquel was established in short-term (6 weeks) controlled trials of adults and one 6-week trial in adolescents (13-17 years) schizophrenic inpatients.* ❖ *The effectiveness of Seroquel in long-term use, that is, for more that 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Seroquel for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.* ❖ *Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex.* *The efficacy of Seroquel in acute bipolar mania was established in two 12-week monotherapy trials in adults, in one 3-week adjunctive trial in adults, and in one 3-week monotherapy trial in paediatric patients (10-17 years).* ❖ *Special Considerations in Treating Paediatric schizophrenia and Bipolar I Disorder* *Paediatric schizophrenia and bipolar I disorder are serious mental disorders, however, diagnosis can be challenging. For paediatric schizophrenia, symptom profiles can be variable, and for bipolar I disorder, patients may have variable patterns of periodicity of manic or mixed symptoms. It is recommended that medication therapy for paediatric schizophrenia and bipolar I disorder be initiated only after a thorough diagnostic evaluation has been performed and careful consideration given to the risks associated with medication treatment. Medication treatment for both paediatric schizophrenia and bipolar I disorder is indicated as part of a total treatment program that often includes psychological, educational and social interventions.* ❖ *Posology:-* ❖ *Schizophrenia:* - *Adolescents (13-17 years)* *Seroquel should be administered twice daily. However, based on response and tolerability Seroquel may be administered three times daily where needed.*	ASTRAZENECA SDN. BHD. LEVEL 12, SURIAN TOWER, 1 JALAN PJU 7/3, MUTIARA DAMANSARA, 47810 PETALING JAYA, SELANGOR

			- *The total daily dose for the initial first five days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3), 300 mg (Day 4) and 400 mg (Day 5). After Day 5, the dose should be adjusted within the recommended dose range of 400 mg/day to 800 mg/day based on response and tolerability. Dosage adjustments should be in increments of no greater than 100 mg/day. Efficacy was demonstrated with Seroquel at both 400mg and 800mg; however, no additional benefit was seen in 800 mg group.* ❖ *Acute manic episode associated with bipolar I disorder:* - *<u>Children and Adolescents (10 to 17 years)</u>* *Seroquel should be administered twice daily. However, based on response and tolerability Seroquel may be administered three times daily where needed.* - *The total daily dose for the initial first five days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3), 300 mg (Day 4) and 400 mg (Day 5). After Day 5, the dose should be adjusted within the recommended dose range of 400 mg/day to 600 mg/day based on response and tolerability. Dosage adjustments should be in increments of no greater than 100 mg/day. Efficacy was demonstrated with Seroquel at both 400mg and 600mg; however, no additional benefit was seen in 600 mg group.* ❖ *Maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex.* - *<u>Children and Adolescents (10 to 17 years)</u>* *The effectiveness of Seroquel for longer than 3 weeks has not been evaluated in controlled clinical trials of children and adolescents. While there is no body of evidence available to answer the question of how long the patient treated with Seroquel should be maintained, it is generally recommended that responding patients be continued beyond the acute response, but at the lowest dose needed to maintain remission. Patients should be periodically reassessed to determine the need for maintenance treatment.* - *<u>Paediatric Use</u>* *In general, the adverse reactions observed in children and adolescents during the clinical trials were similar to those in the adult population with few exceptions. Increases in systolic and diastolic blood pressure occurred in children and adolescents and did not occur in adults. Orthostatic hypotension occurred more frequently in adults (4-7%) compare to children and adolescents (<1%).* ❖ *Schizophrenia* - *The efficacy and safety of Seroquel in the treatment of schizophrenia in adolescents aged 13-17 years were demonstrated in one six week, double-blind, placebo-controlled trial. Safety and*	

			effectiveness of Seroquel in paediatric patients less than 13 years of age with schizophrenia have not been established. ❖ *Maintenance* - *The safety and effectiveness of Seroquel in the maintenance treatment of bipolar disorder has not been established in paediatric patients less than 18 years of age. The safety and effectiveness of Seroquel in the maintenance treatment of schizophrenia has not been established in any patient population, including paediatric patients.* ❖ *Bipolar Mania* - *The efficacy and safety of Seroquel in the treatment of mania in children and adolescents aged 10-17 years with Bipolar I disorder was demonstrated in a 3-week, double-blind, placebo-controlled, multicentre trial. Safety and effectiveness of Seroquel in paediatric patients less than 10 years of age with bipolar mania have not been established.* ❖ *Bipolar Depression* - *Safety and effectiveness of Seroquel in paediatric patients less than 18 years of age with bipolar depression have not been established. Some differences in the pharmacokinetics of quetiapine were noted between children/adolescents (10 to 17 years of age) and adults. When adjusted for weight, the AUC and Cmax of quetiapine were 41% and 39% lower, respectively, in children and adolescents compared to adults. The pharmacokinetics of the active metabolite, norquetiapine, were similar between children/adolescents and adults after adjusting for weight.*	

Products Approved For Additional Indication (DCA 224 – 28 JANUARI 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**BOTOX® (BOTULINUM TOXIN TYPE A) IM INJECTION** (Clostridium botulinum Type A 100 units/vial)	• ***Temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults.***	**Allergan Malaysia Sdn Bhd No 4a Jalan 19/1 46300 Petaling Jaya Selangor**
2.0	2.1 2.2	**MABTHERA CONCENTRATE FOR SOLUTION FOR INFUSION** (Rituximab 100 mg/10ml) **MABTHERA CONCENTRATE FOR SOLUTION FOR INFUSION** (Rituximab 500 mg/50ml)	• ***Non-Hodgkin's Lymphoma*** - ***MabThera is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.***	**Roche (M) Sdn. Bhd. Wisma Selangor Dredging, 142, Jalan Ampang, 50450 Kuala Lumpur**

3.0	3.1 3.2	**ALIMTA INJECTION 100MG** (151.7mg of pemetrexed disodium heptahydrate equivalent to 100mg pemetrexed) **ALIMTA 500MG INJECTION** (713mg of pemetrexed disodium heptahydrate equivalent to 500mg pemetrexed)	• ***ALIMTA is indicated as monotherapy for the maintenance treatment of locally advanced or metatastic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel.***	**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**
4.0	4.1	**IRESSA 250MG** (Gefitinib 250mg)	• ***Iressa is indicated for the first line treatment of adult patients with locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC) who have activating mutations of the EGFR TK.***	**Astrazeneca Sdn. Bhd.** **Ground Floor, Wisma Prima** **17, Jalan Semantan Satu** **50490, Kuala Lumpur**

Products Approved For Additional Indication (DCA 225 – 25 FEBRUARI 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**AVASTIN CONCENTRATE FOR SOLUTION FOR INFUSION** (Bevacizumab 25 mg/ml)	❖ ***Glioblastoma*** • ***Avastin is indicated for the treatment of glioblastoma with progressive disease following prior therapy as a single agent.*** • ***The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin.*** ***Posology:-*** ❖ ***The recommended dose of Avastin is 10mg/kg of body weight given once every 2 weeks as an intravenous infusion.***	**Roche (M) Sdn. Bhd.** **14th Floor, West Block,** **Wisma Selangor Dredging,** **142, Jalan Ampang,** **50450 Kuala Lumpur.**
2.0	2.1 2.2	**PEGASYS PRE-FILLED SYRINGE 135 MCG/0.5 ML** (Penginterferon alfa-2a 135mcg/0.5ml) **PEGASYS PRE-FILLED SYRINGE 180 MCG/0.5ML**	➢ ***For HIV-HCV co-infected patients.*** - ***Chronic Hepatitis C: Pegasys alone or in combination with Copegus (ribavirin) is indicated for the treatment of chronic hepatitis C in non-cirrhotic patients and cirrhotic patients with compensated liver disease, including HCV/HIV co infection patients with stable HIV disease with or without antiretroviral therapy.*** - ***The combination of Pegasys and Copegus is indicated in naïve patients and patients who have failed previous treatment with interferon alfa (pegylated or non-***	**Roche (M) Sdn. Bhd.** **14th Floor, West Block** **Wisma Selangor Dredging** **142, Jalan Ampang** **50450 Kuala Lumpur.**

		(Penginterferon alfa-2a 180mcg/0.5 ml)	***pegylated) alone or in combination with ribavirin.***	
	2.3	**PEGASYS PRE-FILLED SYRINGE 180 MICROGRAM** (Penginterferon alfa-2a 180mcg/0.5 ml)		
	2.4	**PEGASYS PRE-FILLED SYRINGE 135 MICROGRAM** (Penginterferon alfa-2a 135mcg/0.5 ml)		
3.0	3.1	**PEGASYS PRE-FILLED SYRINGE 135 MCG/0.5 ML** (Penginterferon alfa-2a 135mcg/0.5ml)	- ***Chronic Hepatitis C: Pegasys alone or in combination with Copegus (ribavirin) is indicated for the treatment of chronic hepatitis C in non-cirrhotic patients and cirrhotic patients with compensated liver disease, including HCV/HIV co infection patients with stable HIV disease with or without antiretroviral therapy.*** - ***The combination of Pegasys and Copegus is indicated in naïve patients and patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin.***	**Roche (M) Sdn. Bhd.** **14th Floor, West Block** **Wisma Selangor Dredging** **142, Jalan Ampang** **50450 Kuala Lumpur.**
	3.2	**PEGASYS PRE-FILLED SYRINGE 180 MCG/0.5ML** (Penginterferon alfa-2a 180mcg/0.5 ml)		
	3.3	**PEGASYS PRE-**		

<table>
<tr>
<td></td>
<td>3.4</td>
<td>FILLED SYRINGE 180 MICROGRAM (Penginterferon alfa-2a 180mcg/0.5 ml)

PEGASYS PRE-FILLED SYRINGE 135 MICROGRAM (Penginterferon alfa-2a 135mcg/0.5 ml)</td>
<td></td>
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<tr>
<td>4.0</td>
<td>4.1</td>
<td>PEGASYS PRE-FILLED SYRINGE 135 MCG/0.5 ML (Penginterferon alfa-2a 135mcg/0.5ml)</td>
<td>Posology for Chronic Hepatitis C: Genotype 2or 3 LVL with RVR as follows:

Table 1Dosing Recommendations for Combination Therapy for HCV Patients
<table>
<tr><th>Genotype</th><th>Pegasys Dose</th><th>Ribavirin Dose</th></tr>
<tr><td>Genotype 2 or 3 LVL with RVR*</td><td>180 micrograms</td><td>800 mg</td></tr>
</table>
*RVR = rapid viral response (HCV RNA negative) by week 4
LVL = low viral load ≤ 800,000 IU/mL</td>
<td>Roche (M) Sdn. Bhd.
14th Floor, West Block
Wisma Selangor Dredging
142, Jalan Ampang
50450 Kuala Lumpur.</td>
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<td></td>
<td>4.2</td>
<td>PEGASYS PRE-FILLED SYRINGE 180 MCG/0.5ML (Penginterferon alfa-2a 180mcg/0.5 ml)

PEGASYS PRE-</td>
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</table>

	4.3	**FILLED SYRINGE 180 MICROGRAM** (Penginterferon alfa-2a 180mcg/0.5 ml)		
	4.4	**PEGASYS PRE-FILLED SYRINGE 135 MICROGRAM** (Penginterferon alfa-2a 135mcg/0.5 ml)		

Products Approved For Additional Indication (DCA 226 – 25 MAC 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**SOMATULINE P.R. 30 MG INJECTION** (40 mg lanreotide acetate/vial)	❖ ***Treatment of the clinical symptoms of carcinoid tumours.*** ❖ ***Treatment of primary thyrotropic adenomas responsible for hyperthyroidism as a preparation for or as a complement to surgery and/or radiotherapy or where these therapies are unsuitable.***	**Emerging Pharma Sdn Bhd** **Phileo Damansara II 3A03** **Block B, 15 Jalan 16/11** **46350 Petaling Jaya** **Selangor.**

Products Approved For Additional Indication (DCA 227 – 29 APRIL 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**Micardis Tablet 20 mg** (Telmisartan 20mg)	***Cardiovascular Risk Reduction*** ❖ ***MICARDIS is indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors.*** ❖ ***High risk of cardiovascular events can be evidenced by history of coronary artery disease, peripheral arterial disease, stroke, transient ischemic attack, or high-risk diabetes (insulin-dependent or non-insulin dependent) with evidence of end-organ damage. MICARDIS can be used in additional to other needed treatment (such as antihypertensive, antiplatelet or lipid-lowering therapy).*** ❖ ***Studies of Telmisartan in this setting do not exclude that it may not preserve a meaningful fraction of the effect of the ACE inhibitor to which it was compared. Consider using the ACE inhibitor first, and, if it is stopped for cough only, consider re-trying the ACE inhibitor after the cough resolves.*** ❖ ***Use of telmisartan with an ACE inhibitor is not recommended.***	**Boehringer Ingelheim (Malaysia) Sdn. Bhd.** **Suite 15-5, Level 15** **Wisma UOA Damansara II** **No. 6, Jalan Changkat Semantan** **Damansara Heights** **50490 Kuala Lumpur.**
	1.2	**Micardis Tablet 40 mg** (Telmisartan 40mg)		
	1.3	**Micardis Tablet 80 mg** (Telmisartan 80mg)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1	**Seroquel Tablet 25mg** (Quetiapine Fumarate 28.78mg)	❖ ***Prevention of recurrence in patients with bipolar disorder, in patients whose manic or depressive episode has responded to quetiapine treatment.***	**AstraZeneca Sdn Bhd** **Level 12, Surian Tower** **1 Jalan PJU 7/3** **Mutiara Damansara** **47810 Petaling Jaya** **Selangor Darul Ehsan.**
	2.2	**Seroquel Tablet 100mg** (Quetiapine Fumarate 115.13mg)		
	2.3	**Seroquel Tablet 200mg** (Quetiapine Fumarate 230.36mg)		
	2.4	**Seroquel Tablet 300mg** (Quetiapine Fumarate 345.39mg)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.0	3.1	**Seroquel XR Extended Release Tablet 50mg** (57.56mg Quetiapine Fumarate (86.86% quetiapine free base))	❖ ***Seroquel XR is indicated for the prevention of recurrence in patients with bipolar disorder, in patients whose manic or depressive episode has responded to quetiapine treatment.***	**AstraZeneca Sdn Bhd Level 12, Surian Tower 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya Selangor Darul Ehsan.**
	3.2	**Seroquel XR Extended Release Tablet 200mg** (230.26mg Quetiapine Fumarate (86.86% quetiapine free base))		
	3.3	**Seroquel XR Extended Release Tablet 300mg** (345.38mg Quetiapine Fumarate (86.86% quetiapine free base))		
	3.4	**Seroquel XR Extended Release Tablet 400mg** (460.50mg Quetiapine Fumarate (86.86% quetiapine free base))		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
4.0	4.1	**MABTHERA VIALS 100MG/10ML** (Rituximab 100mg/10ml)	❖ ***<u>Chronic Lymphocytic Leukemia (CLL)</u>*** ***MabThera is indicated, in combination with chemotherapy, for the treatment of patients with previously untreated and relapsed/refractory CD20-positive Chronic Lymphocytic Leukemia.***	**Roche (M) Sdn. Bhd. Wisma Selangor Dredging, 142, Jalan Ampang, 50450 Kuala Lumpur.**
	4.2	**MABTHERA VIALS 500MG/50ML** (Rituximab 500mg/50ml)		
	4.3	**MABTHERA 500MG/50ML VIALS** (Rituximab 500mg/50ml)		
	4.4	**MABTHERA 100MG/10ML VIALS** (Rituximab		
	4.5	100mg/10ml)		
		Mabthera Vials 10mg/ml Concentreate For Solution For Infusion (Rituximab 10mg/ml)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
5.0	5.1	**NEUPOGEN PRE-FILLED SYRINGES 30MU/0.5ML** (Recombinant Human Granulocyte Colony-stimulating Factor (Filgrastim) 300mcg/0.5ml)	❖ ***<u>Peripheral blood progenitor cell mobilization (PBPC)</u>*** ***Neupogen® is indicated for the mobilization of peripheral blood progenitor cells in normal volunteers for use in allogeneic peripheral blood progenitor cell transplantation.*** ❖ ***<u>Patients with Acute Myeloid Leukemia (AML)</u>*** ***Neupogen® is indicated to reduce the duration of neutropenia and related clinical sequelae in patients undergoing induction or consolidation chemotherapy.***	**Roche (M) Sdn. Bhd. 14th Floor, West Block, Wisma Selangor Dredging, 142, Jalan Ampang, 50450 Kuala Lumpur.**
	5.2	**NEUPOGEN 30 MIO U 0.3MG/ML VIAL** (Recombinant Human Granulocyte Colony-stimulating Factor (Filgrastim) 30 MIO U 0.3MG/ML)		

Products Approved For Additional Indication (DCA 228 – 27 MEI 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**Crestor 5mg Tablet** (5.2mg rosuvastatin calcium equivalent to 5mg rosuvastatin)	❖ ***Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH): Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C >190mg/dL or >160mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.***	**AstraZeneca Sdn Bhd** **Level 12, Surian Tower** **1 Jalan PJU 7/3** **Mutiara Damansara** **47810 Petaling Jaya** **Selangor Darul Ehsan**
	1.2	**Crestor 10mg Tablet** (10.4mg rosuvastatin calcium equivalent to 10mg rosuvastatin)	❖ ***Posology:-***	
	1.3	**Crestor 20mg Tablet** (20.8mg rosuvastatin calcium equivalent to 20mg rosuvastatin)	***Pediatric Patients (10 to 17 years of age)*** ❖ ***In pediatric patients (10 to 17 years of age) with heterozygous familial hypercholesterolemia the usual dose range of CRESTOR is 5-20 mg/day; the maximum recommended dose is 20mg/day (doses greater than 20mg have not been studied in this patient population). Doses should be individualized according to the recommended goal of therapy. Adjustments should be made at intervals of 4 weeks or more.*** ***Use in children below 10 years*** ❖ ***The safety and effectiveness in children below 10 years of age have not been established. In children and adolescents with homozygous familial hypercholesterolemia experience is limited to eight patients (aged 8 years and above).***	

NO		PRODUCT (ACTIVE	ADDITIONAL INDICATION	MARKETING AUTHORIZATION

		INGREDIENT)		HOLDER
2.0	2.1	**Menopur Powder for Injection and Solvent 75 IU** (Menotrophin, highly purified 75 IU corresponding to 75 IU FSH + 75 IU LH)	❖ ***Hypogonadotrophic hypogonadism in men: MENOPUR may be given in combination with human chorionic gonadotrophin (e.g. Choragon) for the stimulation of spermatogenesis. Patients with primary testicular failure are usually unresponsive.*** ***Posology:-*** ❖ ***Spermatogenesis is stimulated with chorionic gonadotrophin (1000 – 2000 IU two to three times a week) and then menotrophin is given in a dose of 75 or 150 units of FSH with 75 or 150 units of LH two or three times weekly. Treatment should be continued for at least 3 or 4 months.***	**United Italian Trading (M) Sdn Bhd** **No. 1, 2nd Floor** **The Highway Centre,** **Jalan 51/205** **46050 Petaling Jaya** **Selangor**

Products Approved For Additional Indication (DCA 229 – 24 JUN 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**AVASTIN INJECTION 25MG/ML** (Bevacizumab 25mg/ml)	❖ ***Metastatic Breast Cancer (mBC)*** ❖ ***Avastin in combination with paclitaxel or docetaxel is indicated for first line treatment of patients with metastatic breast cancer.***	**Roche (M) Sdn Bhd, The Intermark 182, Jalan Tun Razak 50400 Kuala Lumpur.**
2.0	2.1	**JANUMET 50/500MG (SITAGLIPTIN PHOSPHATE/METFORMIN HCl)** (64.25mg sitagliptin phosphate equivalent to 50mg sitagliptin/500mg metformin HCL)	❖ ***Janumet is indicated as triple combination therapy with a PPARγ agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist.*** ❖ ***Janumet is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dosage of insulin and metformin alone do not provide adequate glycaemic control.*** ❖ ***Posology:-***	**Merck Sharp & Dohme (I.A.) Corp. T2-9 Jaya 33 No 3 (Lot 33) Jalan Semangat Seksyen 13 46100 Petaling Jaya Selangor**
	2.2	**JANUMET 50MG/850MG (SITAGLIPIN PHOSPHATE/METFORMIN HCL)**	❖ ***<u>For patients inadequately controlled on dual combination therapy with the maximal tolerated dose of metformin and a PPARγ agonist</u>*** ***The dose of JANUMET should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken.***	

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER

		(64.25mg sitagliptin phosphate equivalent to 50mg sitagliptin/850mg metformin HCL)	❖ ***<u>For patients inadequately controlled on dual combination therapy with insulin and the maximal tolerated dose of metformin</u>*** ***The dose of JANUMET should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. When JANUMET is used in combination with insulin, a lower dose of insulin may be required to reduce the risk of hypoglycemia.***	
	2.3	**JANUMET 50/1000MG (SITAGLIPTIN PHOSPHATE/METFORMIN HCI)** (64.25mg sitagliptin phosphate equivalent to 50mg sitagliptin/1000mg metformin HCL)		
3.0	3.1	**JANUVIA 25 MG TABLET** (32.13mg sitagliptin monohydrate phosphate equivalent to 25mg sitagliptin)	❖ ***Combination with metformin and PPARγ agonist*** ***JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin and a PPARγ agonist (i.e. thiazolidinediones) when dual therapy with these agent, with diet and exercise, does not provide adequate glycemic control.*** ❖ ***Combination with Insulin*** ***JANUVIA is indicated in patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control in combination with insulin (with or without metformin).***	**Merck Sharp & Dohme (I.A.) Corp.** **T2-9 Jaya 33** **No 3 (Lot 33) Jalan Semangat** **Seksyen 13** **46100 Petaling Jaya** **Selangor**

NO		PRODUCT	ADDITIONAL INDICATION	MARKETING

		(ACTIVE INGREDIENT)		AUTHORIZATION HOLDER
	3.2 3.3	**JANUVIA 50MG TABLET** (64.25mg sitagliptin monohydrate phosphate equivalent to 50mg sitagliptin) **JANUVIA 100MG TABLET** (128.5mg sitagliptin monohydrate phosphate equivalent to 100mg sitagliptin)	❖ ***Posology:-*** ❖ ***The recommended dose of JANUVIA is 100 mg once daily as monotherapy or as combination therapy with metformin, sulfonylurea, insulin (with or without metformin), a PPARγ agonist (i.e. thiazolidinediones), metformin plus a sulfonylurea or metformin plus PPARγ agonist JANUVIA can be taken with or without food.*** ❖ ***When JANUVIA is used in combination with sulfonylurea or with insulin, a lower dosage of sulfonylurea or insulin may be considered to reduce the risk of sulfonylurea or insulin-induced hypoglycaemia.*** ***Because there is a dosage adjustment based upon renal function, assessment of renal function is recommended prior to initiation of JANUVIA and periodically thereafter.***	
4.0	4.1	**LIVIAL TABLET 2.5MG** (Tibolone 2.5mg)	❖ ***Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis.***	**Schering-Plough Sdn Bhd** **T2-9, Jaya 33, No.3 (Lot 33),** **Jalan Semangat, Seksyen 13,** **46100 Petaling Jaya Selangor**

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
5.0	5.1	**YONDELIS 1 MG FOR INJECTION** (Trabectedin 1mg/vial)	❖ ***YONDELIS™ in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.*** ❖ ***Posology:-*** ***For the treatment of ovarian cancer, YONDELIS™ is administered every three weeks as a 3-hour infusion at a dose of 1.1 mg/m^2, immediately after PLD 30 mg/m^2. To minimize the risk of PLD infusion reactions, the initial dose is administered at a rate no greater than 1 mg/minute. If no infusion reaction is observed, subsequent PLD infusions may be administered over a 1-hour period. (See also PLD Summary Product Characteristics for specific administration advice).***	**Johnson & Johnson Sdn Bhd** **Lot 3 & 5, Jalan Tandang** **46050 Petaling Jaya** **Selangor**

Products Approved For Additional Indication (DCA 230 – 29 JULAI 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	Gadovist 1.0 mmol/ml solution for injection (Gadobutrol 604.720mg)	❖ *Gadovist is indicated in adults, adolescents and children aged 2 years and older for:* - *Contrast enhancement during cranial and spinal magnetic resonance imaging (MRI) investigations.* ❖ *Gadovist particularly suitable for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management for detection of very small lesions and for visualization of tumors that do not readily take up contrast media.* ❖ *Gadovist is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischemia and tumor perfusion.* - *Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesion to classify these lesions as benign or malignant.* - *Contrast enhancement in Magnetic Resonance Angiography (CE-MRA).* ❖ *<u>posology :</u>* - *<u>Pediatric patients:</u>* *For children aged 2 years and older and for adolescents the recommended dose is 0.1 mmol Gadovist per kg body weight (equivalent to 0.1 mL Gadovist per kg body weight) for all indications, see section "Indication(s)".* *Gadovist is not recommended for use in children below 2 years of age due to lack of data on safety and efficacy.*	Bayer Co. (M) Sdn Bhd T1-14 Jaya 33, No 3 Jalan Semangat Seksyen 13, 46200 Petaling Jaya Selangor.

Products Approved For Additional Indication (DCA 231 – 26 OGOS 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	GARDASIL SUSPENSION FOR INJECTION (Each 0.5 ml dose contains: HPV* type 6 L1 protein 20 micrograms HPV* type 11 L1 protein 40 micrograms HPV* type 16 L1 protein 40 micrograms HPV* type 18 L1 protein20 micrograms *(HPV = Human Papillomavirus))	*Gardasil is indicated in boys and men 9 through 26 years of age for the prevention of genital warts (condyloma acuminata) caused by HPV types 6 and 11.*	Merck Sharp & Dohme (I.A.) Corp. Malaysia Branch T2-9, Jaya 33, No. 3 (Lot 33), Jalan Semangat, Seksyen 13, 46100 Petaling Jaya, Selangor.

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1	Flixotide Evohaler 50mcg (Fluticasone proprionate 50mcg)	- *Extension of use in <u>children aged 1 to 4 years</u>* ❖ *<u>posology :</u>* *Children aged 1 to 4 years* - *50 to 100 micrograms twice daily* - *Any child who requires prophylactic medication, including patients not controlled on currently available prophylactic medication.* - *Clinical trials in 1 to 4 year old children have shown that the optimal control of asthma symptoms is achieved with 100 micrograms twice daily, administered via a pediatric spacer device with a face mask* - *However, children should be given a starting dose of fluticasone propionate which is appropriate for the severity of their disease, this may be 50 or 100 micrograms twice daily.* - *Once asthma symptoms have been controlled, the dose of fluticasone propionate should be reduced to the lowest dose which maintains control of asthma symptoms.* - *Inhaled FLIXOTIDE is of benefit to younger children in the control of frequent and persistent asthma symptoms.* - *Inhaled FLIXOTIDE is of benefit to younger children in the control of frequent and persistent asthma symptoms.* - *The diagnosis and treatment of asthma should be kept under regular review.*	Glaxosmithkline Pharmaceutical Sdn. Bhd. 8th Floor, Menara Lien Hoe No.8, Persiaran Tropicana 47410 Petaling Jaya Selangor

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
3.0	3.1	Invega 3 mg Extended Release Tablets (Paliperidone 3mg)	➢ *INVEGA™ is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).* *<u>POSOLOGY</u>* ➢ *Schizoaffective Disorder* *The recommended dose of INVEGA™ for the treatment of schizoaffective disorder is 6 mg oral daily, administered in the morning.* ➢ *Initial dose titration is not required. Some patients may benefit from lower or higher doses within the recommended dose range of 3 to 12 mg once daily. A general trend for greater effects was seen with higher doses.* *This trend must be weighed against dose-related increase in adverse reactions. Dosage adjustment, if indicated, should occur only after clinical reassessment. When dose increases are indicated, increments of 3 mg/day are recommended and generally should occur at intervals on more than 4 days. The maximum recommended dose is 12mg/day.*	Johnson & Johnson Sdn Bhd Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya Selangor
	3.2	Invega 6 mg Extended Release Tablets (Paliperidone 6mg)		
	3.3	Invega 9 mg Extended Release Tablets (Paliperidone 9mg)		
	3.4	Invega 12 mg Extended Release Tablets (Paliperidone 12mg)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
4.0	4.1	TARCEVA FILM-COATED TABLET 25 MG (Erlotinib 25mg equivalent to erlotinib hydrochloride 27.32mg)	*Tarceva is indicated as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.*	Roche (Malaysia) Sdn. Bhd. The Intermark, 182, Jalan Tun Razak 50400 Kuala Lumpur
	4.2	Tarceva Film-Coated Tablet 100mg (Erlotinib 100mg equivalent to erlotinib hydrochloride 109.29mg)		
	4.3	Tarceva Film-Coated Tablet 150mg (Erlotinib 150mg equivalent to erlotinib hydrochloride 163.93mg)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
5.0	5.1	Coralan 5mg Film-Coated Tablets (Ivabradine hydrochloride 5.39mg equivalent to Ivabradine 5mg)	*In combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.*	Servier Malaysia Sdn Bhd 1301, Level 13, Uptown 2 47400 Damansara Utama Selangor
	5.2	Coralan 7.5mg Film-Coated Tablets (Ivabradine hydrochloride 8.085mg equivalent to Ivabradine 7.5mg)		

Products Approved For Additional Indication (DCA 232 – 5 Oktober 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	Tykerb Film-Coated Tablets 250mg (Lapatinib ditosylate monohydrate equivalent to 250mg lapatinib)	*TYKERB is indicated in combination with:* • *letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.* *TYKERB in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.* ***Posology*** *Hormone Receptor Positive, HER2 Positive Metastatic Breast Cancer* *The recommended dose of Tykerb is 1500 mg (i.e. six tablets) once daily continuously when taken in combination with letrozole.* *When Tykerb is co-administered with letrozole, the recommended dose of letrozole is 2.5 mg once daily.*	GlaxoSmithKline Pharmaceutical Sdn. Bhd. 8th Floor, Menara Lien Hoe No.8, Persiaran Tropicana 47410 Petaling Jaya Selangor

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
2.0	2.1 2.2 2.3 2.4	Rasilez HCT 150/12.5mg Film-Coated Tablet (Aliskiren 150mg, Hydrochlorothiazide 12.5mg) Rasilez HCT 150/25mg Film-Coated Tablet (Aliskiren 150mg, Hydrochlorothiazide 25mg) Rasilez HCT 300/12.5mg Film-Coated Tablet (Aliskiren 300mg, Hydrochlorothiazide 12.5mg) Rasilez HCT 300/25mg Film-Coated Tablet (Aliskiren 300mg, Hydrochlorothiazide 25mg)	*Rasilez HCT is indicated in the initial treatment of hypertension in patients with moderately to severely increased blood pressure (systolic blood pressure ≥160mmHg and/or diastolic blood pressure ≥100mmHg).* ***Posology*** *Initial treatment of patients with moderately to severe increased blood pressure (≥160mmHg and/or ≥100mmHg)* *For initial treatment, the recommended starting dose is 150mg/12.5mg once daily. If blood pressure remains uncontrolled after 2 to 4 weeks, the dose may be titrated up to a maximum of 300mg/25mg aliskiren/ hydrochlorothiazide. The dose must be determined individually for each patient and adjusted based on the clinical response.*	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	Betaferon Injection (Recombinant interferon beta-1b, 250µg/ml)	*Usage of Betaferon Injection in children and adolescents 12 years and above* ***Posology*** *The inclusion of 5 year follow-up study results of the Betaferon/Betaseron in Newly Emerging multiple sclerosis For Initial Treatment (BENEFIT) study.*	Bayer Co. (M) Sdn Bhd, T1-14 Jaya 33, No 3, Jalan Semangat, Seksyen 13, 46200. Petaling Jaya. Selangor

Products Approved For Additional Indication (DCA 234 – 22 November 2010)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.0	1.1	**HERCEPTIN VIAL 150MG POWDER FOR CONCENTRATE** (Trastuzumab, 21mg/ml)	➢ *Metastatic Gastric Cancer (MGC)* - *Herceptin in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with Human epidermal growth factor receptor 2 (HER2) positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease.* *Herceptin should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by immunohistochemistry (IHC2+) and a confirmatory SISH or FISH (fluorescence in situ hybridization) result, or by an IHC 3+ result. Accurate and validated assay methods should be used.*	ROCHE (MALAYSIA) SDN. BHD., LEVEL 58, THE INTERMARK, 182, JALAN TUN RAZAK, 50400 KUALA LUMPUR WILAYAH PERSEKUTUAN.
	1.2	**HERCEPTIN VIAL 440MG POWDER FOR CONCENTRATE** (Trastuzumab, 21mg/ml)		
	1.3	**HERCEPTIN VIAL 150 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION** (Trastuzumab, 21mg/ml)		

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER

2.0	2.1 2.2 2.3	**Ciprobay 100mg/50ml Infusion** (Ciprofloxacin lactate 127.2mg, corresponding to 100 mg ciprofloxacin) **Ciprobay 200 Infusion 100ml** (Ciprofloxacin lactate 254.4mg, corresponding to 200mg ciprofloxacin) **Ciprobay 400 Infusion Solution** (Ciprofloxacin lactate 508.8mg, corresponding to 400mg ciprofloxacin)	➢ *Consideration should be given to applicable official guidances on the appropriate use of antibacterial agents.* *<u>Children and adolescents</u>* ➢ *Ciprofloxacin may be use in children for the second- and third-line treatment of complicated urinary tract infections and pyelonephritis due to Escherichia coli (age range applied in clinical studies: 1-17 years) and for the treatment of broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa (age applied in clinical studies: 5-17 years).* ➢ *Treatment should only be initiated after careful benefit/risk evaluation, due to possible adverse events related to joints and/or surrounding tissues.* ➢ *The clinical trials in children were performed in the indications listed above. For other indications clinical experience is limited.* ➢ *Infections of the respiratory tract:* *Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, <u>Moraxella catarrhalis</u>, Legionella and Staphylococcus.* *<u>POSOLOGY</u>* *<u>Children and adolescents</u>* • *Cystic fibrosis* ➢ *Clinical and pharmacokinetic data support the use of Ciprofloxacin in pediatric cystic fibrosis patients (aged 5-17 years) with broncho-pulmonary infections associated with Pseudomonas aeruginosa infection, at a dose of 10 mg/kg body weight intravenous three times daily with a maximum of 400 mg per dose.* • *Complicated Urinary Tract Infections and Pyelonephritis* ➢ *For complicated urinary tract infections or pyelonephritis the dose is 6 mg/kg body weight intravenous three times daily to 10 mg/kg body weight intravenous three times daily with a maximum of 400 mg per dose.* *<u>DURATION OF TREATMENT</u>* *<u>Children and adolescents</u>* • *Cystic Fibrosis*	BAYER CO. (MALAYSIA) SDN. BHD. T1-14 JAYA 33 NO.3, JALAN SEMANGAT SEKSYEN 13 46200 PETALING JAYA SELANGOR.

			➢ *For broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa infection in pediatric patients (aged 5-17 years), the duration of treatment is 10-14 days.* • *Complicated Urinary Tract Infections and Pyelonephritis* ➢ *For complicated urinary tract infections or pyelonephritis due to Escherichia coli, the duration of treatment is 10-21 days.* *<u>Children and adolescents</u>* ➢ *Dosing in children and adolescents with impaired renal and or hepatic function has not been studied.*	

NO		PRODUCT (ACTIVE	ADDITIONAL INDICATION	MARKETING AUTHORIZATION

<table>
<tr><th></th><th></th><th>INGREDIENT)</th><th></th><th>HOLDER</th></tr>
<tr><td>3.0</td><td>3.1

3.2</td><td>Ciprobay Tablet 250mg
(Ciprofloxacin hydrochloride monohydrate 291mg, corresponding to 250mg ciprofloxacin)

Ciprobay Tablet 500mg
(Ciprofloxacin hydrochloride monohydrate 582mg, corresponding to 500mg ciprofloxacin)</td><td>➢ Consideration should be given to applicable official guidances on the appropriate use of antibacterial agents.

➢ Prophylaxis of invasive infections due to Neisseria meningitidis.

<u>Children and adolescents</u>
➢ Ciprofloxacin may be use in children for the second- and third-line treatment of complicated urinary tract infections and pyelonephritis due to Escherichia coli (age range applied in clinical studies: 1-17 years) and for the treatment of broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa (age applied in clinical studies: 5-17 years).

➢ Treatment should only be initiated after careful benefit/risk evaluation, due to possible adverse events related to joints and/or surrounding tissues.

➢ The clinical trials in children were performed in the indications listed above. For other indications clinical experience is limited.

➢ Infections of the respiratory tract:
Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, <u>Moraxella catarrhalis</u>, Legionella and Staphylococcus.

<u>POSOLOGY</u>

<u>Adults</u>
➢ Unless otherwise prescribed, the following guideline doses are recommended:

Tablets
<table><tr><td>Prophylaxis of invasive infections due to Neisseria meningitides</td><td>1 x 500mg as a single dose</td></tr></table>
<u>Children and adolescents</u>

• Cystic fibrosis</td><td>Bayer Co. (M) Sdn Bhd,
T1-14 Jaya 33, No 3,
Jalan Semangat,
Seksyen 13,
46200. Petaling Jaya.
Selangor</td></tr>
</table>

			➢ *Clinical and pharmacokinetic data support the use of Ciprofloxacin in pediatric cystic fibrosis patients (aged 5-17 years) with broncho-pulmonary infections associated with Pseudomonas aeruginosa infection, at a dose of 20 mg/kg body weight oral twice daily with a maximum of 750mg per dose.* • *Complicated Urinary Tract Infections and Pyelonephritis* ➢ *For complicated urinary tract infections or pyelonephritis the dose is 10 mg/kg body weight oral twice daily to 20 mg/kg body weight oral twice daily with a maximum of 750mg ciprofloxacin per dose.* *<u>DURATION OF TREATMENT</u>* *<u>Children and adolescents</u>* • *Cystic Fibrosis* ➢ *For broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa infection in pediatric patients (aged 5-17 years), the duration of treatment is 10-14 days.* • *Complicated Urinary Tract Infections and Pyelonephritis* ➢ *For complicated urinary tract infections or pyelonephritis due to Escherichia coli, the duration of treatment is 10-21 days.* *<u>Children and adolescents</u>* *Dosing in children and adolescents with impaired renal and or hepatic function has not been studied.*	

NO		PRODUCT (ACTIVE	ADDITIONAL INDICATION	MARKETING AUTHORIZATION

		INGREDIENT)		HOLDER
4.0	4.1	**Dotarem Injection (10ml vial)** (Per 10ml:- Gadoteric Acid 2.7932g corresponding to: • DOTA 2.0246g • Gadolinium Oxide 0.9062g)	➢ *Angiography* *<u>POSOLOGY</u>* ➢ *Dotarem should always be administered by medically qualified personnel.* ➢ *The doses are determined by the physician and are adapted to each individual's needs.* ➢ *The recommended dose is 0.2mL/kg (0.1mmol/kg) in adults, children and infants.* ➢ *Angiography: Dotarem is not recommended for angiography in children under 18 years of age due to insufficient data on efficacy and safety in this indication.* ➢ *In angiography, depending on the results of the examination being performed, a second injection may be administered during the same session if necessary.* ➢ *In some exceptional cases, as in the confirmation of isolated metastasis or the detection of leptomeningeal tumours, a second injection of 0.4ml/kg (0.2mmol/kg) can be administered.* ➢ *This medicinal product must be administered by intravenous injection only. It must not be injected via the subarachnoid (or epidural) route.* *This product is for single use.*	Medi-Diagnostic Solutions (M) Sdn Bhd. No 17-1, Jalan PJU 1/3C Sunwaymas Commercial Centre 47301 Petaling Jaya Selangor
	4.2	**Dotarem Injection (20ml vial)** (Per 20ml:- Gadoteric Acid 5.5864g corresponding to: • DOTA 4.0496g • Gadolinium Oxide 1.8124g)		

NO		PRODUCT	ADDITIONAL INDICATION	MARKETING

<table>
<tr><th></th><th></th><th>(ACTIVE INGREDIENT)</th><th></th><th>AUTHORIZATION HOLDER</th></tr>
<tr><td>5.0</td><td>5.1</td><td>RENVELA (SEVELAMER CARBONATE) TABLET 800MG
(Sevelamer carbonate 800mg)</td><td>

Renvela is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.
Renvela is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus >1.78mmol/L.
Renvela should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

<u>POSOLOGY</u>

**Table 1. Starting Dose for Patients Not Taking a Phosphate Binder
<table>
<tr><td>Serum Phosphorus</td><td>Renvela 800mg</td></tr>
<tr><td>> 1.78 and < 2.42mmol/L</td><td>1 tablet three times daily with meals</td></tr>
<tr><td>≥ 2.42 and < 2.91mmol/L</td><td>2 tablet three times daily with meals</td></tr>
<tr><td>≥ 2.91mmol/L</td><td>2 tablet th□ee times daily with meals</td></tr>
</table>
** The word “dialysis” in Table 1 has been removed.
</td><td>DKSH MALAYSIA SDN BHD
NO. 74, JALAN UNIVERSITI
46200 PETALING JAYA
SELANGOR</td></tr>
</table>

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
6.0	6.1	**Valcyte Tablets 450mg** (Valganciclovir 450mg as 496.3mg valganciclovir HCl)	*POSOLOGY* ➢ *Prevention of CMV disease in transplantation* - *For kidney transplant patients, the recommended dose is 900mg once daily starting within 10 days of transplantation until 200 days post-transplantation.*	ROCHE (MALAYSIA) SDN. BHD. LEVEL 58, THE INTERMARK, 182, JALAN TUN RAZAK 50400 KUALA LUMPUR