**Maklumat tambahan indikasi untuk upload pada laman web**
**Year 2014**
**Products Approved For Additional Indication (DCA 275 – 9 Mei 2014)**

| NO | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
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| 1. | 1.1 **Trajenta Duo 2.5mg/500mg Film-Coated Tablets**<br>[Linagliptin 2.5mg & metformin hydrochloride 500mg]<br><br>1.2 **Trajenta Duo 2.5mg/850mg Film-Coated Tablets**<br>[ Linagliptin 2.5mg & metformin hydrochloride 850mg ]<br><br>1.3 **Trajenta Duo 2.5mg/1000mg Film-Coated Tablets**<br>[Linagliptin 2.5mg & metformin hydrochloride 1000mg] | ➢ Indication:<br><br>*Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.*<br><br>➢ Posology:<br><br>*For patients currently not treated with metformin*<br>*In patients currently not treated with metformin, initiate treatment with 2.5mg linagliptin/500mg metformin hydrochloride twice daily***.** | **BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.**<br>Suite 15-5, Level 15 Wisma UOA Damansara II<br>No.6, Jalan Changkat Semantan,<br>Damansara Heights, 50490 Kuala Lumpur |
| 2. | 2.1 **Afinitor 2.5mg Tablet**<br>[Everolimus 2.5mg]<br><br>2.2 **Afinitor 5mg Tablet**<br>[ Everolimus 5mg ]<br><br>2.3 **Afinitor 10mg Tablet**<br>[Everolimus 10mg] | ➢ Indication:<br><br>*Treatment of adult and paediatric patients, 1 year of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates for curative surgical resection.*<br><br>➢ Posology:<br><br>*Pediatric Use*<br>*Paediatric use of Afinitor is recommended for patients 1 year of age and older with TSC for the treatment of SEGA that requires therapeutic intervention but cannot be curatively resected. The safety and effectiveness of Afinitor have not been established in paediatric patients with renal angiomyolipoma with TSC in the absence of SEGA.*<br><br>*The effectiveness of AFINITOR in paediatric patients with SEGA was demonstrated in two* | **NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.**<br>Level 22, Tower B, Plaza 33<br>No.1, Jalan Kemajuan,<br>Seksyen 13<br>46200 Petaling Jaya,<br>Selangor |

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| | | *clinical trials based on demonstration of durable objective response, as evidenced by reduction in SEGA tumour volume. Improvement in disease-related symptoms and overall survival in paediatric patients with SEGA has not been demonstrated. The long term effects of Afinitor on growth and pubertal development are unknown.*<br><br>*Study 1 was a randomized, double-blind, multicenter trial comparing Afinitor (n=78) to placebo (n=39) in paediatric and adult patients. The median age was 9.5 years (range 0.8 to 26 years). At the time of randomization, a total of 20 patients were < 3 years of age, 54 patients were 3 to < 12 years of age, 27 patients were 12 to < 18 years of age, and 16 patients were ≥ 18 years of age. The overall nature, type, and frequency of adverse reactions across the age groups evaluated were similar, with the exception of a higher per patient incidence of infectious serious adverse events in patients < 3 years of age. A total of 6 of 13 patients (46%) < 3 years of age had at least one serious adverse event due to infection, compared to 2 of 7 patients (29%) treated with placebo. No patient in any age group discontinued Afinitor due to infection. Subgroup analyses showed reduction in SEGA volume with Afinitor treatment in all paediatric age subgroups.*<br><br>*Study 2 was an open-label, single-arm, single-center trial of Afinitor (N=28) in patients aged ≥ 3 years; median age was 11 years (range 3 to 34 years). A total of 16 patients were 3 to < 12 years, 6 patients were 12 to < 18 years, and 6 patients were ≥ 18 years. The frequency of adverse reactions across the age groups was generally similar. Subgroup analyses showed reductions in SEGA volume with Afinitor treatment in all paediatric age subgroups.*<br><br>*Everolimus clearance normalized to body surface area was higher in paediatric patients than in adults* | |

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| | | *with SEGA. The recommended starting dose and subsequent requirement for therapeutic drug monitoring to achieve and maintain trough concentrations of 5 to 15 ng/mL are the same for adult and paediatric patients with SEGA.* | |
| 3. | 3.1 **Eylea 40mg/ml Solution For Injection In Vial**<br>[Aflibercept 40mg/mL]<br><br>3.2 **Eylea 40mg/ml Solution For Injection In Prefilled Syringe**<br>[Aflibercept 40mg/mL] | ➢ Indication:<br><br>*Eylea is indicated for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO).*<br><br>➢ Posology:<br><br>*The recommended dose for Eylea is 2 mg aflibercept, equivalent to 0.05mL (50 µL).*<br>*After the initial injection, treatment is given monthly. The interval between two doses should not be shorter than one month.*<br>*If there is no improvement in visual and anatomic outcomes over the course of the first three injections, continued treatment is not recommended.*<br>*Monthly treatment continues until visual and anatomic outcomes are stable for three monthly assessments. Thereafter the need for continued treatment should be reconsidered.*<br>*If necessary, treatment may be continued with gradually increasing treatment intervals to maintain a stable visual and anatomic outcome. If treatment has been discontinued, visual and anatomic outcomes should be monitored and treatment should be resumed if these deteriorate.*<br><br>*Usually, monitoring should be done at the injection visits. During treatment interval extension through to completion of therapy, the monitoring schedule should be determined by the treating physician based on the individual patient's response and may be more frequent than the schedule of injections.* | **BAYER CO. (MALAYSIA) SDN. BHD.**<br>T1-14 Jaya 33, No.3,<br>Jalan Semangat, Seksyen 13,<br>46200 Petaling Jaya,<br>Selangor |

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| 4. | 4.1 **Ilaris 150mg Powder For Solution For Injection**<br>[Canakinumab 150mg/ml] | ➢ Indication:<br><br>*Ilaris is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.*<br><br>➢ Posology:<br><br>*The recommended dose of Ilaris for SJIA patients with body weight ≥ 7.5 kg is 4 mg/kg (up to a maximum of 300 mg) administered every four weeks via subcutaneous injection.* | **NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.**<br>Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor |
| 5. | 5.1 **Apidra 100 U/ml- Solution For Injection In Vial**<br>[Insulin glulisine 100U/ml] | ➢ Posology:<br><br><u>*Posology*</u><br>*The potency of this preparation is stated in units. These units are exclusive to Apidra and are not the same as IU or the units used to express the potency of other insulin analogues.*<br>*Apidra should be used in regimens that include an intermediate or long acting insulin or basal insulin analogue and can be used with oral hypoglycaemic agents.*<br>*The dose of Apidra should be individually adjusted.*<br><br><u>*Method of administration*</u><br>*Intravenous use*<br>*Apidra can be administered intravenously under medical supervision for glycemic control with close monitoring of blood glucose and serum potassium to avoid hypoglycemia and hypokalemia..*<br>*Apidra must not be mixed with glucose or Ringer's solution or with any other insulin.*<br><br>*Subcutaneous use*<br>*Apidra should be given by subcutaneous injection shortly (0-15 min) before or soon after meals or by continuous subcutaneous pump infusion.* | **SANOFI-AVENTIS (MALAYSIA) SDN. BHD.**<br>Level TB-18-1, Tower B, Plaza 33<br>No.1, Jalan Kemajuan, Seksyen 13<br>46200 Petaling Jaya, Selangor |

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| | | *Apidra should be administered subcutaneously in the abdominal wall, thigh or deltoid or by continuous infusion in the abdominal wall. Injection sites and infusion sites within an injection area (abdomen, thigh or deltoid) should be rotated from one injection to the next. The rate of absorption, and consequently the onset and duration of action, may be affected by the injection site, exercise and other variables. Subcutaneous injection in the abdominal wall ensures a slightly faster absorption than other injection sites.*<br>*Care should be taken to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Patients must be educated to use proper injection techniques.*<br><br>*Mixing with insulins*<br>*When administered as a subcutaneous injection, Apidra must not be mixed with other medicinal products except NPH human insulin.*<br><br>*Continuous subcutaneous insulin infusion*<br>*Apidra may be used for Continuous Subcutaneous Insulin Infusion (CSII) in pump systems suitable for insulin infusion with the appropriate catheters and reservoirs. Patients using CSII should be comprehensively instructed on the use of the pump system.*<br>*The infusion set and reservoir used with Apidra must be changed at least every 48 hours using aseptic technique. These instructions may differ from general pump manual instructions. It is important that patients follow the Apidra specific instructions when using Apidra. Failure to follow Apidra specific instructions may lead to serious adverse events.*<br>*When used with a subcutaneous insulin infusion pump, Apidra must not be mixed with diluents or any other insulin.*<br>*Patients administering Apidra by CSII must have an alternative insulin delivery system available* | |

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| 6. | 6.1 **LANTUS SOLOSTAR 100IU/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN**<br>[Insulin Glargine 100IU/ml]<br><br>6.2 **LANTUS FOR OPTIPEN 100 UNITS/ML,3ML CARTRIDGES**<br>[Insulin Glargine 100IU/ml]<br><br>6.3 **LANTUS 100 UNITS/ML,10ML VIALS**<br>[Insulin Glargine 100IU/ml]<br><br>6.4 **LANTUS 100 UNITS/ML OPTISET**<br>[Insulin Glargine 100IU/ml] | ➢ Indication:<br><br>*Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.*<br><br>➢ Posology:<br><br>*Lantus contains insulin glargine, an insulin analogue, and has a prolonged duration of action. Lantus should be administered once daily at any time but at the same time each day.*<br><br>*The Lantus dose regimen (dose and timing) should be individually adjusted. In patients with type 2 diabetes mellitus, Lantus can also be given together with orally active antidiabetic medicinal products. The potency of this medicinal product is stated in units. These units are exclusive to Lantus and are not the same as IU of the units used to express the potency of other insulin analogues.*<br><br>*<u>Special Population</u>*<br>*Elderly population*<br>*In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.*<br><br>*Renal Impairment*<br>*In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism.*<br><br>*Hepatic Impairment*<br>*In patients with hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.*<br><br>*Paediatric Population*<br>*Safety and efficacy of Lantus have been established in adolescents and children aged 2 years and older. Lantus has not been studied in children below the age of 2 years.* | **SANOFI-AVENTIS (MALAYSIA) SDN. BHD.**<br>Level TB-18-1, Tower B, Plaza 33<br>No.1, Jalan Kemajuan, Seksyen 13<br>46200 Petaling Jaya, Selangor |

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| 7. | 7.1 **MYOZYME POWDER FOR SOLUTION FOR INJECTION**<br>[Alglucosidase alfa 52.5mg/vial] | ➢ Indication:<br><br>*Myozyme is indicated for long-term enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency).*<br><br>*Myozyme is indicated in adults and paediatric patients of all ages* | **SANOFI-AVENTIS (MALAYSIA) SDN. BHD.**<br>Level TB-18-1, Tower B, Plaza 33<br>No.1, Jalan Kemajuan, Seksyen 13<br>46200 Petaling Jaya, Selangor |