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Year 2015
Products Approved For Additional Indication (DCA 286 – 3 April 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	**1.1 EXELON PATCH 5** [Rivastigmine base (Each patch of 5cm2 contains 9mg rivastigmine base, in vivo release rate of 4.6mg/ 24 hours)] **1.2 EXELON PATCH 10** [Rivastigmine base (Each patch of 10cm2 contains 18mg rivastigmine base, in vivo release rate of 9.5mg/ 24 hours) **1.3 EXELON PATCH 15** [Rivastigmine base (Each patch of 15cm2 contains 27mg rivastigmine base, in vivo release rate of 13.3mg/ 24 hours)]	➢ Indication: *Treatment of patients with severe dementia of the Alzheimer's type.* ➢ Posology: *Severe dementia of the Alzheimer's type* *Initial dose and dose titration to the effective dose: Treatment is started with Exelon Patch 5 once a day. Subsequently the dose should be increased to Exelon Patch 10 and then to Exelon Patch 15 which is the demonstrated effective dose. These dose increases should always be based on good tolerability of the current dose and may be considered only after a minimum of four weeks of treatment at each dose level.*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya Selangor
2.	**2.1 VICTOZA 6MG/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN** [Liraglutide 6.0 mg/ml]	➢ Indication: *Victoza is indicated for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control:* *In combination with:* *Metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea.* *In combination with:* *Metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy.* *Combination therapy with metformin and a basal insulin in patients not achieving adequate glycaemic control with Victoza® and metformin.*	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Unit A-9-2, Level 9, Tower A Menara UOA Bangsar No.5, Jalan Bangsar Utama 1 59000 Kuala Lumpur

3.	**3.1 LEVEMIR FLEXPEN 100U/ML, 3ML** [Insulin detemir 100 U/ml]	➢ Indication: *Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.* ➢ Posology: *Levemir® is a soluble, basal insulin analogue with a flat and predictable action profile with a prolonged duration of effect. Levemir® can be use alone as the basal insulin or in combination with bolus insulin. It can also be used in combination with oral antidiabetic medicines or as add-on therapy to liraglutide treatment.* *Dosage* *In combination with oral antidiabetic agents or as add-on to liraglutide, it is recommended to initiate Levemir® treatment with once daily administration at a dose of 10 U or 0.1-0.2 U/kg. The dose of Levemir® should be titrated based on individual patients' needs.* *Based on study results, the following titration guideline is recommended:* *When Levemir® is used as part of a basal-bolus insulin regimen, Levemir® should be administered once or twice daily depending on patients' needs.*	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Unit A-9-2, Level 9, Tower A Menara UOA Bangsar No.5, Jalan Bangsar Utama 1 59000 Kuala Lumpur

Average pre-breakfast SMPG	*Levemir® dose adjustment*
> 10.0 mmol/L (180 mg/dL)	*+ 8*
9.1-10.0 mmol/L (163-180 mg/dL)	*+ 6*
8.1-9.0 mmol/L (145-162 mg/dL)	*+ 4*
7.1-8.0 mmol/L (127-144 mg/dL)	*+ 2*
6.1-7.0 mmol/L (109-126 mg/dL)	*+ 2*
If one SMPG measurement	
3.1-4.0 mmol/L (56-72 mg/dL)	*- 2*
<3.1 mmol/L (<56 mg/dL)	*- 4*

For patients who require twice daily dosing to optimise the blood glucose control, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose.

Transfer from other insulins: Transfer to Levemir® from intermediate or long-acting insulins may require adjustment of dose and timing of administration. As with all insulins, close glucose monitoring is recommended during the transition and in the initial weeks thereafter.

Concomitant antidiabetic treatment may need to be adjusted (dose and timing of concurrent short-acting insulins or the dose of oral antidiabetic agents).

Pregnancy
Treatment with Levemir® can be considered during pregnancy, if the benefit justifies possible risks. One randomised controlled clinical trial in pregnant women with type 1 diabetes compared Levemir® (n=152) to NPH insulin (n=158), both in combination with insulin aspart. The results showed similar efficacy of insulin detemir and NPH insulin and a similar overall safety profile during pregnancy, on pregnancy outcomes as well as on the foetus and the newborn. Post-marketing data from an additional approximately 300 outcomes from pregnant women exposed to Levemir® indicate no adverse effects of insulin detemir on pregnancy and no malformative or foeto/neonatal toxicity of insulin detemir.

Animal data do not indicate reproductive toxicity.

In general, intensified blood glucose control and monitoring of pregnant women with diabetes are recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimester. After delivery, insulin requirements normally return rapidly to pre-pregnancy values.

Lactation
It is unknown whether insulin detemir is excreted in human milk. No metabolic effects of ingested insulin detemir on the

		breast-fed newborn/infant are anticipated since insulin detemir, as a peptide, is digested into amino acids in the human gastrointestinal tract. Breast-feeding women may require adjustments in insulin dose and diet.	