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Year 2013
Products Approved For Additional Indication (DCA 268 – 26 September 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **GADOVIST 1.0 MMOL/ML SOLUTION FOR INJECTION** [Gadobutrol 1.0 mmol (equivalent to gadobutrol 604.72 mg)]	➢ Indication: *Gadovist can also be used for MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.* ➢ Posology: *Whole body MRI (except MRA)* *In general, the administration of 0.1 ml Gadovist per kg body weight is sufficient to answer the clinical question.*	**BAYER CO. (MALAYSIA) SDN. BHD.** T1-14 Jaya 33, No.3, Jalan Semangat, Seksyen 13, 46200 Petaling Jaya, Selangor
2.	2.1 **Onglyza Tablet 2.5 mg** [Saxagliptin Hydrochloride 2.79 mg (equivalent to saxagliptin 2.5 mg)] 2.2 **Onglyza Tablet 5 mg** [Saxagliptin Hydrochloride 5.58 mg (equivalent to saxagliptin 5 mg)]	➢ Indication: *Onglyza is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control:* *as triple oral therapy in combination with* • *metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.*	**ASTRAZENECA SDN. BHD.** Level 12, Surian Tower, 1 Jalan PJU 7/3 Mutiara Damansara, 47810 Petaling Jaya, Selangor.
3.	3.1 **GALVUS 50 MG TABLETS** [Vildagliptin 50mg]	➢ Indication: *Galvus is indicated in the treatment of type 2 diabetes mellitus:* *As triple therapy in combination with* • *A sulphonylurea and metformin when diet and exercise plus dual therapy with these*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, CREST, 3 Two Square No.2, Jalan 19/1 46300 Petaling Jaya, Selangor

		medicinal products do not provide adequate glycaemic control. *Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.* ➢ Posology: *When used as monotherapy in combination with metformin, in combination with thiazolidinedione, in combination with metformin and sulphonylurea or in combination with insulin (with or without metformin), the recommended daily dose of vildagliptin is 100mg, administered as one dose of 50mg in the morning and one dose of 50 mg in the evening.* *When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia.* *If a dose of Galvus is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.* *The safety and efficacy of vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione has not been established.*	
4.	4.1 **GALVUS MET 50/500MG FILM-COATED TABLET** [Vildagliptin 50mg & Metformin Hydrochloride 500mg (eq. to 390 mg metformin)] 4.2 **GALVUS MET 50/850MG FILM-COATED TABLET** [Vildagliptin 50mg & Metformin Hydrochloride 850mg (eq. to 660 mg metformin)]	➢ Indication: *Galvus Met is indicated in the treatment of type 2 diabetes mellitus:* • *Galvus Met is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea.* • *Galvus Met is indicated in triple combination therapy with insulin as an adjunct to diet and*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, CREST, 3 Two Square No.2, Jalan 19/1 46300 Petaling Jaya, Selangor

	4.3 **GALVUS MET 50/1000MG FILM-COATED TABLET** [Vildagliptin 50mg & Metformin Hydrochloride 1000mg (eq. to 780 mg metformin)]	*exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.* ➢ Posology: *The dose of antihyperglycaemic therapy with Galvus Met should be individualised on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg vildagliptin. Galvus Met may be initiated at either the 50 mg/500 mg, 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening.* • *For patients inadequately controlled at their maximal tolerated dose of metformin monotherapy: The starting dose of Galvus Met should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken.* • *For patients switching from co-administration of vildagliptin and metformin as separate tablets: Galvus Met should be initiated at the dose of vildagliptin and metformin already being taken.* • *For patients inadequately controlled on dual combination with metformin and a sulphonylurea: The doses of Galvus Met should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. When Galvus Met is used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia.* • *For patients inadequately controlled on dual combination therapy with insulin and the*	

		maximal tolerated dose of metformin: The dose of Galvus Met should provide vildagliptin dose as 50mg twice daily (100mg total daily dose and a dose of metformin similar to the dose already being taken. *The safety and efficacy of vildagliptin and metformin as triple oral therapy in combination with a thiazolidinedione have not been established.* *Elderly (≥ 65 years)* *As metformin is excreted via the kidney, and elderly patients have a tendency to decreased renal function, elderly patients taking Galvus Met should have their renal function monitored regularly.* *Paediatric patients (< 18 years)* *Galvus Met is not recommended for use in children and adolescents (<18 years). The safety and efficacy of Galvus Met in children and adolescents have not been established. No data are available.*	