NOVARTIS

GALVUS®

(vildagliptin)

50 mg Tablets

Basic Succinct Statement

CODE: BSS RD 28 NOV 2016; APPR 13 JUN 2017

This material is only meant for Healthcare Professionals

GALVUS®

Important note: Before prescribing, consult full prescribing information.

Presentation: Tablets containing 50 mg of Vildagliptin.

Indications: Galvus is indicated in the treatment of type 2 diabetes mellitus:

As monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual therapy in combination with

- metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin
- a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

As triple therapy in combination with

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these 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.

Vildagliptin is also indicated as initial combination therapy with metformin in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.

Dosage: 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 50 mg in the morning and one dose of 50 mg in the evening. When used in dual combination with a sulphonylurea, the recommended dose of vildagliptin is 50 mg once daily administered in the morning. In this patient population, vildagliptin 100 mg daily was no more effective than vildagliptin 50 mg once daily. When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. When used as initial combination therapy with metformin, the recommended dose of Galvus is 50mg once or twice daily. Doses higher than 100mg are not recommended. 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. Galvus can be administered with or without a meal. No dosage adjustment is required in patients with mild renal impairment (creatinine clearance ≥ 50 ml/min). In patients with moderate or severe renal impairment or with end-stage renal disease (ESRD), the recommended dose of Galvus is 50 mg once daily. Galvus should not be used in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3X the upper limit of normal. No dose adjustments are necessary in elderly patients. Galvus is not recommended for use in children and adolescents due to a lack of data on safety and efficacy.

Contraindications: Hypersensitivity to vildagliptin or to any of the excipients**.**

Warnings/Precautions: ♦Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. ♦Not recommended in patients with hepatic impairment including patients with a pre-treatment ALT or AST >3X the upper limit of normal. Liver function tests (LFT) to be performed prior to treatment initiation, at three-month intervals during the first year and periodically thereafter. Withdrawal of therapy with Galvus recommended if an increase in AST or ALT of 3X upper limit normal or greater persist. Following withdrawal of treatment with Galvus and LFT normalisation, treatment with Galvus should not be reinitiated. ♦Generally not recommended in patients with NYHA Class III unless the benefits outweigh the potential risks. ♦Not recommended in patients with NYHA Class IV.

Women of child-bearing potential, pregnancy: Not to be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Breast-feeding: Not to be used.

Special excipients: Contains lactose.

Interactions: ♦Vildagliptin has a low potential for drug interactions. ♦No clinically relevant interactions with other oral antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin.

Adverse reactions:
♦Rare cases of angioedema. Rare cases of hepatic dysfunction (including hepatitis) ♦**Monotherapy** - Common: dizziness - Uncommon: hypoglycaemia, constipation, headache, edema peripheral, arthralgia, sometimes severe. ♦**Combination with metformin** - Common: hypoglycaemia, headache, tremor, dizziness, nausea. ♦**Combination with a sulphonylurea** - Common: hypoglycaemia, headache, tremor, dizziness, asthenia. ♦**Combination with a thiazolidinedione** - Common: weight increase, edema peripheral - Uncommon: headache, asthenia, hypoglycemia. ♦**Combination with insulin** - Common: decreased blood glucose, headache, chills, nausea, gastroesophageal reflux disease – Uncommon: Diarrhea, flatulence. ♦**Combination with metformin and a sulphonylurea** - Common: dizziness, tremor, asthesia, hypoglycemia, hyperhidrosis. ♦**Post-marketing experience:** - Not known: hepatitis (reversible with drug discontinuation), abnormal liver function tests, urticaria, bullous or exfoliative skin lesions including bullous pemphigoid, pancreatitis, arthralgia, sometimes severe.