NOVARTIS

GALVUS MET®

(vildagliptin and metformin fixed combination)

50 mg/500 mg, 50 mg/850 mg, 50 mg/1,000 mg Tablets

Basic Succinct Statement

CODE: BSS RD 28 NOV 2016; APPR 12 NOV 2018

This material is only meant for Healthcare Professionals

GALVUS MET®

Important note: Before prescribing, consult full prescribing information.

Presentation: Vildagliptin/Metformin hydrochloride fixed combination: 50 mg/500 mg, 50 mg/850 mg, 50 mg/1,000 mg tablets.

Indications: Galvus Met is indicated in the treatment of type 2 diabetes mellitus:
♦treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. ♦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. ♦in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. ♦as an initial therapy in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.

Dosage: ♦Do not exceed the maximum recommended daily dose of 100 mg vildagliptin. Galvus Met may be initiated at any one of the tablet strength twice daily, one tablet in the morning and the other in the evening. ♦Should be given with meals.♦**Adults:** Starting dose for patients inadequately controlled at their maximal tolerated dose of metformin monotherapy or on dual combination therapy with insulin and maximal tolerated dose of metformin: Galvus Met should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. ♦Starting dose 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. ♦Starting dose for treatment naïve patients: 50mg/500mg once daily and gradually titrated to a maximum dose of 50mg/1000mg twice daily after assessing adequacy of therapeutic response. ♦**Renal impairment:** Dosage adjustment may be required in patients with creatinine clearance between 30 and 90 mL/min. ♦**Hepatic impairment:** Galvus Met should not be used in patients with hepatic impairment, including those with pre-treatment aminotransferase (ALT) or aspartate aminotransferase (AST) > 3 times the upper limit of normal (ULN). ♦**Geriatric patients:** Dosage should be adjusted based on renal function which needs to be monitored. ♦**Children (under 18 years of age):** Not recommended.

Contraindications: ♦Hypersensitivity to the active substances or to any of the excipients. ♦Acute or chronic metabolic acidosis including lactic acidosis or diabetic ketoacidosis with or without coma. ♦patients with creatinine clearance < 30 ml/min. ♦Acute conditions with the potential to alter renal function. ♦Acute or chronic disease which may cause tissue hypoxia. ♦Hepatic impairment. ♦Acute alcohol intoxication, alcoholism. ♦Breast-feeding.

Warnings/Precautions: ♦Risk of lactic acidosis. ♦Monitoring of renal function before treatment initiation and regularly thereafter. ♦Caution with concomitant use of medications that

may affect renal function or metformin hydrochloride disposition. ♦Should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials. ♦Discontinue treatment in case of hypoxemia ♦Temporary discontinuation in patients undergoing surgical procedure. ♦Excessive alcohol intake to be avoided. ♦Not recommended in patients with hepatic impairment including patients with a pre-treatment ALT or AST >3x the upper limit of normal. ♦Risk of decreased vitamin B_{12} serum levels. ♦Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. ♦Risk of skin lesions, including blistering and ulceration. ♦Risk of acute pancreatitis. ♦Risk of hypoglycemia. ♦ Elderly patients taking Galvus Met should have their renal function monitored regularly ♦Not recommended in pediatric patients. ♦Severe and disabling arthralgia in patients taking DPP-4 inhibitors

Adverse reactions:

♦**Vildagliptin**: Rare cases of angioedema. Rare cases of hepatic dysfunction (including hepatitis). ♦**Vildagliptin monotherapy** - Common: dizziness – Uncommon: hypoglycaemia, headache, constipation, edema peripheral. ♦**Metformin monotherapy** – Very common: nausea, vomiting, diarrhoea, abdominal pain, loss of appetite. Common: metallic taste. Very rare: decrease of vitamin B12 absorption, lactic acidosis, liver function test abnormalities, hepatitis, skin reactions such as erythema, pruritus and urticaria. ♦Other effects with **combination of Vildagliptin and Metformin** - Common: headache, tremor, dizziness, hypoglycaemia, nausea. ♦Other effects with **combination of Vildagliptin and Metformin with insulin –** Common: headache, chills, nausea, gastroesophageal reflux disease, decreased blood glucose – Uncommon: diarrhea, flatulence. ♦Other effects with **combination of Vildagliptin and Metformin with a sulphonylurea –** Common: dizziness, tremor, asthenia, hypoglycemia, hyperhidrosis. ♦**Post-marketing experience:** - Unknown: hepatitis (reversible with drug discontinuation), abnormal liver function tests, urticaria, bullous and exfoliative skin lesions including bullous pemphigoid, pancreatitis, arthralgia, sometimes severe.