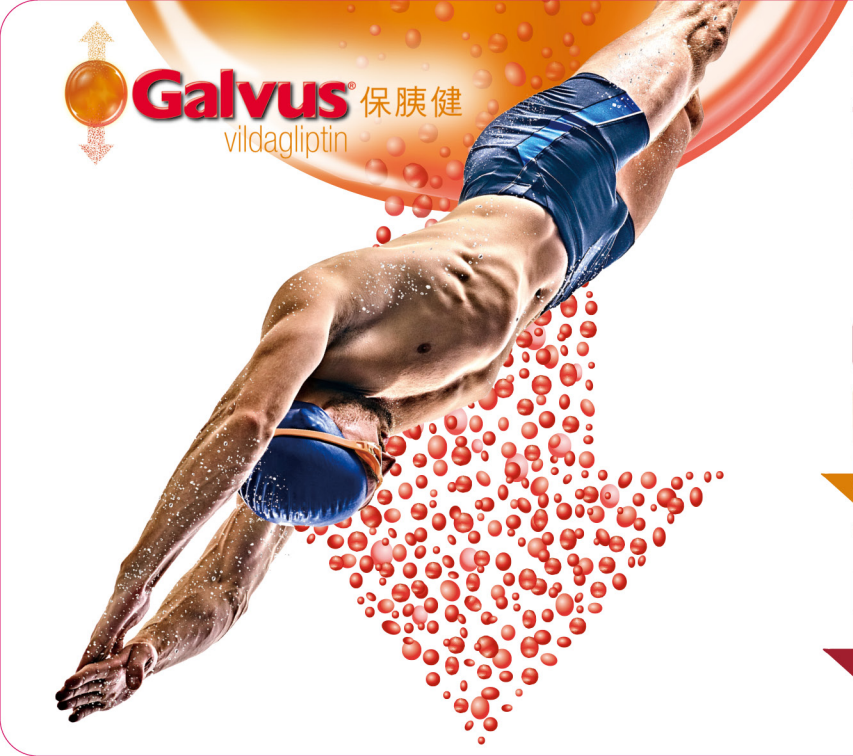
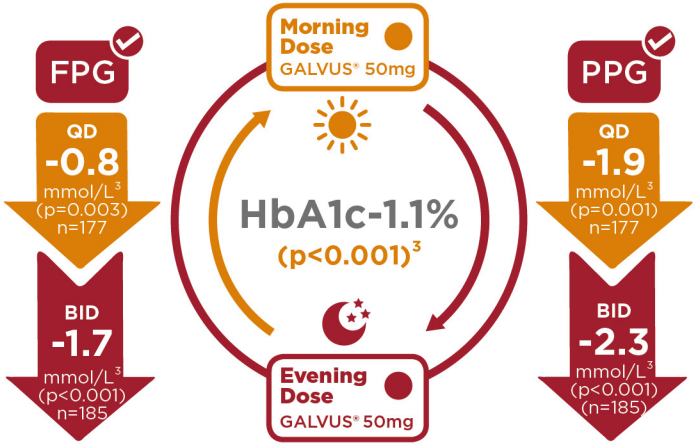


GALVUS® extends the meal-induced increase in GLP-1 levels into the inter-meal and overnight periods[1,2]



Dosage recommendation[3-6]

Special population	50mg QD	50mg BID
Elderly (including > 75 years old)	✔	✔
Congestive heart failure (NYHA functional class I-III)	✔	✔
Moderate or severe renal impairment or with end-stage renal disease (ESRD)	✔	Galvus 保胰健 vildagliptin

Galvus® Important note: Before prescribing, consult full prescribing information. **Presentation:** Vildagliptin. Tablets: 50 mg. **Indications:** Galvus® is indicated in the treatment of type 2 diabetes mellitus in adults as: ♦ **Monotherapy:** in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. ♦ **Dual oral therapy** in combination with • metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin; • 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; • thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. ♦ **Triple oral 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. **Dosage:** ♦ When used as monotherapy, in combination with metformin, in combination with thiazolidinedione, in combination with metformin and a sulphonylurea, or in combination with insulin (with or without metformin) the recommended daily dose of vildagliptin is 100 mg, 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 in the morning. A lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. ♦ Doses higher than 100 mg are not recommended. ♦ Can be administered orally with or without a meal. ♦ In patients with moderate or severe renal impairment or with End Stage Renal Disease (ESRD), the recommended dose is 50 mg once daily. ♦ Galvus® should not be used in patients with hepatic impairment. ♦ **Children (under 18 years of age):** not recommended. **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. ♦ Use with caution in patients with ESRD on haemodialysis. ♦ Should not be used in patients with hepatic impairment including patients with a pre-treatment ALT or AST> 3x ULN. ♦Liver function tests (LFT) should be performed prior to treatment initiation, at three-month intervals during the first year and periodically thereafter. Withdrawal of therapy with Galvus® is recommended if an increase in AST or ALT of 3X ULN or greater persists. Following withdrawal of treatment with Galvus® and LFT normalisation, treatment with Galvus® should not be reinitiated. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus® ♦ Clinical experience in patients with NYHA functional class III treated with vildagliptin is still limited and results are inconclusive ♦ Not recommended in patients with NYHA Class IV♦ Recommended monitoring for skin disorders such as blistering or ulceration. ♦ Discontinue vildagliptin if pancreatitis is suspected. If acute pancreatitis is confirmed, vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. ♦ Lower dose of sulphonylurea may be considered when treated in combination to reduce risk of hypoglycaemia. ♦ Patients with problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this product. **Pregnancy:** Should not be used. **Breast-feeding:** Should not be used. **Interactions:** ♦ Vildagliptin has a low potential for drug interactions. ♦ No clinically relevant interactions with other oral antidiabetics (pioglitazone, metformin and glyburide), digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin were observed after co-administration with vildagliptin. **Adverse reactions:** ♦ Rare cases of hepatic dysfunction (including hepatitis). Rare cases of angioedema. ♦ Combination with metformin • Common: hypoglycaemia, tremor, headache, dizziness, nausea; • Uncommon: fatigue. ♦ Combination with a sulphonylurea • Common: hypoglycaemia, tremor, headache, dizziness, asthenia; • Uncommon: constipation • Very rare: nasopharyngitis. ♦ **Combination with a thiazolidinedione** • Common: weight increase, oedema peripheral; • Uncommon: hypoglycaemia, headache, asthenia. ♦ **Monotherapy** • Common: dizziness; • Uncommon: hypoglycaemia, headache, edema peripheral, constipation, arthralgia; • Very rare: upper respiratory tract infection, nasopharyngitis. ♦ **Combination with metformin and a sulphonylurea** • Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia; ♦ **Combination with insulin** • Common: decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease; • Uncommon: diarrhoea, flatulence. ♦ **Post-marketing experience:** • Frequency not known: abnormal liver function tests, hepatitis (reversible with drug discontinuation), urticaria, pancreatitis, bullous or exfoliative skin lesions including bullous pemphigoid. **Packs:** 28's and 56's **Legal classification:** P1S1S3 Ref: EMA July 2014 + CDS 0843s (Nov 2016)

References: 1. Ahrén B et al. Mechanisms of action of the dipeptidyl peptidase-4 inhibitor vildagliptin in humans. Diabetes Obes Metab 2011;13:775–783. **2.** Foley JE. Med Chem 2014; 4: 439–40. doi: 10.4172/2161-0444.1000176. **3.** Bosi E, et al. Diabetes Care 2007; 30: 890–5. **4.** Product information - Galvus. **5.** Schweizer A, et al. Diabetes Obes Metab 2011; 13: 55–64. 6. Lukashevich V, et al. Diabetes Obes Metab 2011; 13: 947–54.

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Galvus® 保胰健 vildagliptin

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