JANUVIA®
sitagliptin

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (tel: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Film-coated tablets containing either 25 mg, 50 mg or 100 mg of sitagliptin

USES
For adult patients with type 2 diabetes mellitus Januvia is indicated to improve glycaemic control:
as monotherapy
- in patients inadequately controlled by diet and exercise alone and for whom metformin is contraindicated or not tolerated

as dual oral therapy in combination with
- metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control
- a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is contraindicated or not tolerated
- a PPARγ agonist when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control

as 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
- a PPARγ agonist and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Januvia is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dosage of insulin do not provide adequate glycaemic control.

DOSAGE AND ADMINISTRATION
One 100 mg tablet once daily. When used in combination with metformin and/or a PPARγ agonist, maintain the dosage of metformin and/or PPARγ agonist, and administer sitagliptin concomitantly. When used in combination with a sulphonylurea or with insulin, consider a lower dose of sulphonylurea or insulin, to reduce risk of hypoglycaemia. Renal impairment: glomerular filtration rate [GFR] ≥45 to < 90 ml/min: no dosage adjustment required; GFR ≥30 to <45 mL/min: 50 mg once daily; GFR <30 mL/min including those with end-stage renal disease (ESRD) requiring haemodialysis or peritoneal dialysis: 25 mg once daily. Sitagliptin may be administered without regard to the timing of dialysis. Because of the above dosage adjustment, assessment of renal function is recommended prior to initiation of sitagliptin and periodically thereafter. When used with other anti-diabetic agent(s) in renal impairment, refer to SmPC(s) of the other agent(s). Hepatic impairment: mild to moderate hepatic impairment: no dosage adjustment necessary; severe hepatic impairment: no data available, exercise caution. Elderly: no dosage adjustment necessary. Children and adolescents <18 years: no data available.

CONTRAINDICATIONS
Hypersensitivity to active substance or excipients.

PRECAUTIONS
Do not use in patients with type 1 diabetes or for diabetic ketoacidosis. Use of DPP-4 inhibitors has been associated with a risk of acute pancreatitis and very rarely cases of necrotizing or haemorrhagic pancreatitis and/or death have been reported with sitagliptin. Inform patients of the symptoms of acute pancreatitis. If pancreatitis is suspected, sitagliptin and other potentially suspect medicinal products should be discontinued. If acute pancreatitis is confirmed, sitagliptin should not be restarted. Caution should be exercised in patients with a history of pancreatitis. On addition of sitagliptin to insulin or a sulphonylurea, consider a lower dose of insulin or sulphonylurea to reduce the risk of hypoglycaemia. Lower dosages are

recommended in patients with GFR < 45 mL/min including ESRD patients requiring haemodialysis or peritoneal dialysis. Serious hypersensitivity reactions have been reported, including anaphylaxis, angioedema and exfoliative skin conditions including Stevens-Johnson syndrome. Onset occurred within the first 3 months after initiation of treatment with some reports occurring after the first dose. If suspected, discontinue sitagliptin, assess for other potential causes and initiate alternative treatment for diabetes. Cases of bullous pemphigoid have been reported. If suspected, discontinue sitagliptin.

Drug interactions:

Digoxin: monitor patients at risk of toxicity.

Pregnancy and Lactation:

Do not use during pregnancy or breast-feeding.

SIDE EFFECTS Refer to SmPC for complete information on side effects

Serious adverse reactions including pancreatitis and hypersensitivity reactions have been reported. Hypoglycemia has been reported in combination with sulphonylurea and insulin. Sitagliptin monotherapy: *Common:* upper respiratory tract infection, nasopharyngitis, osteoarthritis, pain in extremity, hypoglycaemia, headache. Combination with metformin: *Common:* nausea, flatulence, vomiting. Combination with a sulphonylurea: *Common:* hypoglycaemia. Combination with metformin and a sulphonylurea: *Very common*: hypoglycaemia; *Common*: constipation. Combination with a PPARγ agonist (pioglitazone): *Common*: flatulence, peripheral oedema. Combination with a PPARγ agonist (pioglitazone) and metformin: *Common:* peripheral oedema. Combination with insulin with/ without metformin: *Common:* hypoglycaemia, influenza. *Serious adverse events with sitagliptin during post-approval use alone and/or with other diabetes medicines: Rare:* thrombocytopenia. *Frequency not known:* hypersensitivity reactions including anaphylactic responses (see precautions), interstitial lung disease, acute pancreatitis, fatal and non-fatal haemorrhagic and necrotizing pancreatitis, angioedema, cutaneous vasculitis, exfoliative skin conditions including Stevens-Johnson syndrome, impaired renal function, acute renal failure.

PACKAGE QUANTITIES AND BASIC NHS COST

25 mg x 28 tablets: £33.26;
50 mg x 28 tablets: £33.26;
100 mg x 28 tablets: £33.26

Marketing Authorisation Number

25 mg: EU/1/07/383/002;
50 mg: EU/1/07/383/008;
100 mg: EU/1/07/383/014

Marketing Authorisation Holder

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

Legal Category: **POM**

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