Janvia™

Tablet

Sitagliptin (as Phosphate Monohydrate) USP

COMPOSITION

Janvia™ 50: Each film-coated tablet contains Sitagliptin Phosphate Monohydrate USP 64.25 mg equivalent to 50 mg of Sitagliptin.
Janvia™ 100: Each film-coated tablet contains Sitagliptin Phosphate Monohydrate USP 128.50 mg equivalent to 100 mg of Sitagliptin.

PHARMACOLOGY

Janvia™ (Sitagliptin) is an oral diabetes medicine that helps to control blood sugar levels. Janvia (Sitagliptin) tablets contain the active ingredient Sitagliptin, which is a type of medicine called dipeptidyl peptidase 4 (DPP-4) inhibitor. It is used to treat people with type 2 or non-insulin dependent diabetes mellitus (NIDDM).

INDICATION

Janvia™ (Sitagliptin) is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is also indicated for use in combination with Metformin, Sulfonylurea or Thiazolidinediones when diet and exercise plus the single agent does not provide adequate glycemic control.

DOSAGE AND ADMINISTRATION

Route of administration : Oral.
The recommended dose of Sitagliptin is 100 mg daily. Sitagliptin can be taken with or without food.
Patients with Renal Insufficiency
For patients with mild renal insufficiency, no dosage adjustment for Sitagliptin is required. For patients with moderate renal insufficiencey, the dose of Sitagliptin is 50 mg once daily. For patients with severe renal insufficiency or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis, the dose of Sitagliptin is 25 mg once daily.
Pediatric Use : Safety and effectiveness of Sitagliptin in pediatric patients under 18 years of age have not been established.
Geriatric Use : No dosage adjustment is required based solely on age. The drug is excreted by the kidney. As elderly patients are more likely to have decreased renal function, caution should be taken in dose selection in the elderly.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATION

History of a serious hypersensitivity reaction to Sitagliptin, such as anaphylaxis or angioedema and exfoliative skin conditions including Stevens-Johnson syndrome.

PRECAUTION

If pancreatitis is suspected, Sitagliptin should promptly be discontinued and appropriate management should be initiated. Dosage adjustment should recommended in patients with moderate or severe renal insufficiency and in patients with ESRD. Assessment of renal function should recommend prior to initiating Sitagliptin. When Sitagliptin is used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, a lower dose of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia. If a hypersensitivity reaction is suspected, Sitagliptin should be discontinued.

SIDE EFFECTS

Common : The most common adverse reactions are; upper respiratory tract infection, nasopharyngitis and headache. Hypoglycemia may occur in patients treated with the combination of Sitagliptin and sulfonylurea and add-on to insulin.
Rare : Severe allergic reactions (rash, hives, itching, difficulty swallowing or breathing, tightness in the chest, swelling of the mouth, face, lips, throat, or tongue, unusual hoarseness), chest pain or discomfort, decreased urination, dizziness or light-headedness, fast or difficult breathing, feeling of being unusually cold, general feeling of being unwell, muscle pain or weakness, red, blistered, swollen, or peeling skin, slow or irregular heartbeat, symptoms of pancreas inflammation (eg, severe stomach or back pain with or without nausea or vomiting), unusual drowsiness, unusual or persistent stomach pain or discomfort; unusual tiredness or weakness.

USE IN PREGNANCY AND LACTATION

Pregnancy : Pregnancy Category: B. Safety of Sitagliptin in pregnant women has not been established. Sitagliptin should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.
Nursing mother : It is not known whether Sitagliptin is excreted in human milk, because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

DRUG INTERACTION

With medicine : Co-administration of Digoxin and Sitagliptin may slightly increase the mean peak drug concentration of Digoxin. But no dosage adjustment of Digoxin or Sitagliptin is recommended.
With food & others : There are no established drug-food interaction.

OVERDOSE

The administration of an excessive dose results in hypoglycemia (refer to warnings) which should be treated immediately by the administration of sugar. If the patient is unconscious, immediately inform a doctor and call the emergency service.

STORAGE

Store below 30^0 C and in dry place, protected from light.
Keep all medicines out of reach of children.

PACKING

Janvia™ 50 : Each box contains 3x10 tablets in Alu-Alu blister strip.
Janvia™ 100 : Each box contains 1x10 tablets in Alu-Alu blister strip.

*** Further information is available on request.**

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness