

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE



Read this carefully before you start taking **JANUVIA**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JANUVIA**[®].

What is JANUVIA[®] used for?

JANUVIA[®] is used in addition to diet and exercise to improve blood sugar levels in adult patients with type 2 diabetes mellitus:

- alone in patients who cannot take metformin
- in combination with metformin
- in combination with metformin and a sulfonylurea (e.g. glyburide, gliclazide or glimepiride)
- in combination with premixed or long/intermediate acting insulin (with or without metformin)
- in combination with pioglitazone (with or without metformin)

How does JANUVIA[®] work?

JANUVIA[®] contains the medicinal ingredient sitagliptin which belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). JANUVIA[®] helps to improve the levels of insulin when blood sugar level is high, especially after a meal. JANUVIA[®] also helps to decrease the amount of sugar made by the body. JANUVIA[®] is unlikely to cause low blood sugar (**hypoglycemia**).

What are the ingredients in JANUVIA[®]?

Medicinal ingredient: sitagliptin (as sitagliptin phosphate monohydrate)

Non-medicinal ingredients: Anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (macrogol), polyvinyl alcohol, propyl gallate, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide and yellow iron oxide.

JANUVIA[®] comes in the following dosage forms:

Tablets: 25 mg, 50 mg, 100 mg

Do not use JANUVIA[®] if:

- you are allergic (hypersensitive) to sitagliptin or any of the other ingredients in JANUVIA[®].

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JANUVIA[®]. Talk about any health conditions or problems you may have, including if you:

- have or have had pancreatitis (inflammation of the pancreas);

- have risk factors for pancreatitis such as:
 - gallstones (solid particles that form in the gall bladder),
 - a history of alcoholism,
 - high triglyceride levels;
- have type 1 diabetes;
- have or have had diabetic ketoacidosis (increased ketones in the blood or urine);
- have or have had kidney problems;
- have liver problems;
- had an organ transplant;
- have human immunodeficiency syndrome (HIV);
- are pregnant or plan to become pregnant; JANUVIA® is not recommended for use during pregnancy;
- are breastfeeding or plan to breastfeed. It is not known if JANUVIA® passes into breast milk.

Other warnings you should know about:

Serious Skin Reactions and Pancreatitis:

- **JANUVIA® can cause serious side effects, including:**
 - **Pancreatitis** (inflammation of the pancreas) which can be life-threatening and cause death.
 - **Serious Skin Reactions** called **Stevens-Johnson syndrome** and **bullous pemphigoid**. These reactions can happen after your first dose or up to 3 months after you start JANUVIA®.

See the **Serious side effects and what to do about them** table, below for more information on these and other serious side effects.

Hypoglycemia (low blood sugar):

- When JANUVIA® is used with metformin and a sulfonylurea medicine or with insulin (with or without metformin), **hypoglycemia** (low blood sugar) can occur. Lower doses of the sulfonylurea medicine or insulin may be required while you take JANUVIA®. You should use caution when driving or using machines if you are taking JANUVIA® with a sulfonylurea medicine or with insulin.

Blood Tests:

JANUVIA® may cause abnormal blood tests. Your healthcare professional will do blood tests before you start JANUVIA® and while you are taking it. They may check your blood sugar, liver function and how well your kidneys are working. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

How to take JANUVIA®:

- Take JANUVIA® exactly as your healthcare professional tells you to.
- JANUVIA® can be taken with or without food.

Usual adult dose:

100 mg once daily. Your healthcare professionals may adjust your dose if you have kidney problems.

Overdose:

If you think you, or a person you are caring for, have taken too much JANUVIA®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of JANUVIA® to make up for a missed dose.

What are possible side effects from using JANUVIA®?

These are not all the possible side effects you may feel when taking JANUVIA®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Stuffy or runny nose
- Sore throat
- Vomiting
- Constipation
- Headache
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

Serious side effects and what to do about them			
Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hypoglycemia (low blood sugar – when used with metformin and a sulfonylurea, or when used with insulin with or without metformin): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		X	

Serious side effects and what to do about them			
Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Pancreatitis (inflammation of the pancreas): prolonged severe stomach pain and possible vomiting.			X
Allergic reactions: rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			X
Serious skin reactions including Stevens-Johnson syndrome, bullous pemphigoid: blisters or breakdown of your skin.		X	
Acute kidney failure (sometimes requiring dialysis): nausea, loss of appetite and weakness, pass little or no urine, breathlessness.			X
VERY RARE			
Rhabdomyolysis (breakdown of damaged muscle): muscle spasms, weakness, red-brown (tea-coloured) urine.			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15°C to 25°C).

Keep out of reach and sight of children.

If you want more information about JANUVIA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html> or the Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

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