

PART III: CONSUMER INFORMATION

 **JANUVIA**[®]
sitagliptin tablets
(as sitagliptin phosphate monohydrate)

This leaflet is Part III of a three-part “Product Monograph” published when JANUVIA[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JANUVIA[®]. Contact your physician or pharmacist if you have any questions about the drug.

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your physician has prescribed this medicine only for you. Never give it to anyone else.

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

JANUVIA[®] is a member of 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 is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and/or does not use the insulin that your body produces as well as it should. When this happens, sugar (glucose) builds up in the blood. This can lead to serious problems.

When it should not be used:

Do not take JANUVIA[®] if you are allergic to any of the ingredients in JANUVIA[®].

What the medicinal ingredient is:
sitagliptin phosphate monohydrate

What the non-medicinal ingredients are:

Each film-coated tablet of JANUVIA[®] contains the following inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and yellow iron oxide.

What dosage forms it comes in:

Tablets: Each tablet contains 25, 50 or 100 mg sitagliptin.

WARNINGS AND PRECAUTIONS

BEFORE you use JANUVIA[®] talk to your physician or pharmacist if:

- you have or have had pancreatitis (inflammation of the pancreas);
- you have risk factors for pancreatitis such as:
 - gallstones (solid particles that form in the gall bladder),
 - a history of alcoholism,
 - high triglyceride levels;
- you have type 1 diabetes;
- you have or have had diabetic ketoacidosis (increased ketones in the blood or urine);
- you are taking a sulfonylurea. When JANUVIA[®] is used in combination with a sulfonylurea and metformin, or in combination with insulin (with or without metformin), low blood sugar can occur. Your physician may consider lowering the dose of the sulfonylurea or insulin. Take precautions to avoid low blood sugar while driving or using machinery.
- you have or have had an allergic reaction to JANUVIA[®];
- you have or have had kidney problems;
- you have liver problems;
- you had an organ transplant;
- you have human immunodeficiency syndrome (HIV);
- you are pregnant or plan to become pregnant; JANUVIA[®] is not recommended for use during pregnancy;
- you are breast-feeding or plan to breast-feed. It is not known if JANUVIA[®] passes into breast milk.

JANUVIA[®] is not recommended for use in patients under 18 years of age.

JANUVIA[®] may cause abnormal kidney function.

Cases of inflammation of the pancreas (**pancreatitis**) have been reported in patients taking JANUVIA[®]. Pancreatitis can be severe and lead to death.

Cases of **serious skin reactions** can occur and have been reported in patients taking JANUVIA®. These skin reactions are called **Stevens-Johnson syndrome** and **bullous pemphigoid**. They can happen after the first dose or up to 3 months on the drug. You may need treatment in a hospital. You may need to see a dermatologist to diagnose and treat these skin reactions.

INTERACTIONS WITH THIS MEDICATION

Tell your physician or pharmacist about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

PROPER USE OF THIS MEDICATION

Take JANUVIA® exactly as your physician has prescribed.

Usual adult dose:

100 mg once daily by mouth with or without food. The daily dose may be adjusted in patients with kidney problems.

Overdose:

If you think you have taken too much JANUVIA®, contact your health care 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® on the same day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects of JANUVIA® include:

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

When JANUVIA® is used with metformin and a sulfonylurea medicine, or with insulin (with or without metformin), low blood sugar (hypoglycemia) can occur. Lower doses of the sulfonylurea medicine or insulin may be required while you use JANUVIA®.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	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.		√	
Rare			
Pancreatitis (inflammation of the pancreas): prolonged severe stomach pain and possible vomiting.			√
Allergic reactions: rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			√
Serious skin reactions including Stevens-Johnson syndrome, bullous pemphigoid: blisters or breakdown of your skin.		√	
Acute kidney failure (sometimes requiring dialysis): nausea, loss of appetite and weakness, pass little or no urine, breathlessness.			√

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.

HOW TO STORE IT

Store at room temperature (15°C to 30°C).

Keep JANUVIA® and all medicines safely away from children.

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.

MORE INFORMATION

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 Consumer Information by visiting the [Health Canada website](#) or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to JANUVIA®, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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