

IMPORTANT: PLEASE READ

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™ is used in combination with metformin to improve blood sugar levels in adult patients with type 2 diabetes mellitus in addition to diet and exercise.

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 important non-medicinal ingredients are:

Each film-coated tablet of JANUVIA™ contains the following inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, 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 100 mg sitagliptin.

WARNINGS AND PRECAUTIONS

BEFORE you use JANUVIA™ talk to your physician or pharmacist if:

- you have type 1 diabetes.
- you have or have had diabetic ketoacidosis (increased ketones in the blood or urine).

- you have or have had an allergic reaction to JANUVIA™.
- you have congestive heart failure.
- you have or have had kidney problems.
- you have liver problems.
- 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 children under 18 years of age.

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 dose:

100 mg once daily by mouth with or without food.

Overdose:

If you take more than the prescribed dosage of JANUVIA™, contact your physician or poison control centre immediately.

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

Like all medicines, JANUVIA™ may cause side effects.

The most common side effects of JANUVIA™ include: stuffy or runny nose and sore throat.

Tell your physician or pharmacist if you develop any unusual side effects, or any of the above side effects that do not go away or gets worse.

The following additional side effects have been reported in general use with JANUVIA™:

- Allergic reactions, which may be serious, including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking JANUVIA™ and call your physician right away. Your physician may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.

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	
Rare	Allergic reactions including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			√

This is not a complete list of side effects. For any unexpected effects while taking JANUVIA™, contact your physician or pharmacist.

HOW TO STORE IT

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

Keep JANUVIA™ and all medicines safely away from children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free telephone: 1-866-234-2345

Toll-free fax: 1-866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office Marketed
Health Products Safety and Effectiveness
Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

or Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail: Merck Frosst Canada Ltd.

P.O. Box 1005

Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Before contacting Health Canada or Merck Frosst, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merckfrosst.com> or by contacting the sponsor, Merck Frosst Canada Ltd., at: 1-800-567-2594.

This leaflet was prepared by Merck Frosst Canada Ltd.

Last revised: December 13, 2007

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www.merckfrosst.com



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for a better tomorrow.

MERCK FROSST CANADA LTD.
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