

Patient Information
JANUVIA™ (jah-NEW-vee-ah)
(sitagliptin)

Tablets

Read the Patient Information that comes with JANUVIA* before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

What is JANUVIA?

JANUVIA is a prescription medicine used along with diet and exercise to lower blood sugar in **adult** patients with type 2 diabetes. JANUVIA may be taken alone or along with certain other medicines to control blood sugar.

- JANUVIA lowers blood sugar when blood sugar is high, especially after a meal. JANUVIA also lowers blood sugar between meals.
- JANUVIA helps to improve the levels of insulin produced by your own body after a meal.
- JANUVIA decreases the amount of sugar made by the body. JANUVIA is unlikely to cause your blood sugar to be lowered to a dangerous level (hypoglycemia) because it does not work when your blood sugar is low.

JANUVIA has not been studied in children under 18 years of age.

JANUVIA has not been studied with insulin, a medicine known to cause low blood sugar.

Who should not take JANUVIA?

Do not take JANUVIA if you:

- **have had an allergic reaction to JANUVIA.**

JANUVIA should not be used to treat patients with:

- Type 1 diabetes.
- Diabetic ketoacidosis (increased ketones in the blood or urine).

What should I tell my doctor before and during treatment with JANUVIA?

Tell your doctor about all of your medical conditions, including if you:

- **have had an allergic reaction to JANUVIA.**
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if JANUVIA will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant. If you use JANUVIA during pregnancy, talk with your doctor about how you can be on the JANUVIA registry. The toll-free telephone number for the pregnancy registry is: 1-800-986-8999.
- are breast-feeding or plan to breast-feed. It is not known if JANUVIA will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking JANUVIA.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take JANUVIA?

- Take JANUVIA exactly as your doctor tells you to take it.
- Take JANUVIA by mouth once a day.
- Take JANUVIA with or without food.
- If you have kidney problems, your doctor may prescribe lower doses of JANUVIA. Your doctor may perform blood tests on you from time to time to measure how well your kidneys are working.
- Your doctor may prescribe JANUVIA along with certain other medicines that lower blood sugar.
- 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 two doses of JANUVIA at the same time.**
- If you take too much JANUVIA, call your doctor or local Poison Control Center right away.
- **When your body is under some types of stress, such as fever, trauma (such as a car accident), infection or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.**
- Monitor your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking JANUVIA.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and complications of diabetes.
- Your doctor will monitor your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

What are the possible side effects of JANUVIA?

The most common side effects of JANUVIA include:

- Upper respiratory infection
- Stuffy or runny nose and sore throat
- Headache

JANUVIA may occasionally cause stomach discomfort and diarrhea.

When JANUVIA is used in combination with another type of diabetes medicine known as a sulfonylurea, low blood sugar (hypoglycemia) due to the sulfonylurea can occur. Your doctor may prescribe lower doses of the sulfonylurea medicine.

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 doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.**

Tell your doctor if you have any side effect that bothers you or that does not go away.

Other side effects may occur when using JANUVIA. For more information, ask your doctor.

How should I store JANUVIA?

- Store JANUVIA at room temperature, 68 to 77°F (20 to 25°C).

Keep JANUVIA and all medicines out of the reach of children.

General information about the use of JANUVIA

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use JANUVIA for a condition for which it was not prescribed. Do not give JANUVIA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about JANUVIA. If you would like to know more information, talk with your doctor. You can ask your doctor or pharmacist for additional information about JANUVIA that is written for health professionals. For more information call 1-800-622-4477.

What are the ingredients in JANUVIA?

Active ingredient: sitagliptin

Inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, and sodium stearyl fumarate. The tablet film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and yellow iron oxide.

What is type 2 diabetes?

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

The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness, and amputation.

High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

Revised October 2007

Manufactured for:

 MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

Manufactured by:

Merck Sharp & Dohme (Italia) S.p.A.
Via Emilia, 21
27100 – Pavia, Italy
97627XX