

Patient Information
JANUMET™ (JAN-you-met)
(sitagliptin/metformin HCl)

Tablets

Read the Patient Information that comes with JANUMET¹ 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 the most important information I should know about JANUMET?

Metformin hydrochloride, one of the ingredients in JANUMET, can cause a rare but serious side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital.

Stop taking JANUMET and call your doctor right away if you get any of the following symptoms of lactic acidosis:

- You feel very weak and tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have unexplained stomach or intestinal problems with nausea and vomiting, or diarrhea.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a slow or irregular heart beat.

You have a higher chance of getting lactic acidosis if you:

- have kidney problems.
- have liver problems.
- have congestive heart failure that requires treatment with medicines.
- drink a lot of alcohol (very often or short-term “binge” drinking).
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and don’t drink enough fluids.
- have certain x-ray tests with injectable dyes or contrast agents.
- have surgery.
- have a heart attack, severe infection, or stroke.
- are 80 years of age or older and have not had your kidney function tested.

What is JANUMET?

JANUMET tablets contain two prescription medicines, sitagliptin (JANUVIA™²) and metformin. JANUMET can be used along with diet and exercise to lower blood sugar in adult patients with type 2 diabetes. Your

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doctor will determine if JANUMET is right for you and will determine the best way to start and continue to treat your diabetes.

JANUMET:

- helps to improve the levels of insulin after a meal.
- helps the body respond better to the insulin it makes naturally.
- decreases the amount of sugar made by the body.
- is unlikely to cause low blood sugar (hypoglycemia) when it is taken by itself to treat high blood sugar.

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

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

Who should not take JANUMET?

Do not take JANUMET if you:

- **have type 1 diabetes.**
- **have certain kidney problems.**
- **have conditions called metabolic acidosis or diabetic ketoacidosis** (increased ketones in the blood or urine).
- **have had an allergic reaction to JANUMET or sitagliptin (JANUVIA), one of the components of JANUMET.**
- **are going to receive an injection of dye or contrast agents for an x-ray procedure,** JANUMET will need to be stopped for a short time. Talk to your doctor about when to stop JANUMET and when to start again. See "*What is the most important information I should know about JANUMET?*"

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

JANUMET may not be right for you. Tell your doctor about all of your medical conditions, including if you:

- have kidney problems.
- have liver problems.
- have had an allergic reaction to JANUMET or sitagliptin (JANUVIA), one of the components of JANUMET.
- have heart problems, including congestive heart failure.
- are older than 80 years. Patients over 80 years should not take JANUMET unless their kidney function is checked and it is normal.
- drink alcohol a lot (all the time or short-term "binge" drinking).
- are pregnant or plan to become pregnant. It is not known if JANUMET 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 JANUMET during pregnancy, talk with your doctor about how you can be on the JANUMET 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 JANUMET will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking JANUMET.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. JANUMET may affect how well other drugs work and some drugs can affect how well JANUMET works.

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. Talk to your doctor before you start any new medicine.

How should I take JANUMET?

- Your doctor will tell you how many JANUMET tablets to take and how often you should take them. Take JANUMET exactly as your doctor tells you.
- Your doctor may need to increase your dose to control your blood sugar.
- Your doctor may prescribe JANUMET along with a sulfonylurea (another medicine to lower blood sugar). See "*What are the possible side effects of JANUMET?*" for information about increased risk of low blood sugar.
- Take JANUMET with meals to lower your chance of an upset stomach.
- Continue to take JANUMET as long as your doctor tells you.
- If you take too much JANUMET, call your doctor or poison control center right away.
- If you miss a dose, take it with food 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 JANUMET at the same time.

- **You may need to stop taking JANUMET for a short time. Call your doctor for instructions if you:**
 - are dehydrated (have lost too much body fluid). Dehydration can occur if you are sick with severe vomiting, diarrhea or fever, or if you drink a lot less fluid than normal.
 - plan to have surgery.
 - are going to receive an injection of dye or contrast agent for an x-ray procedure.

See "*What is the most important information I should know about JANUMET?*" and "*Who should not take JANUMET?*"

- **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 JANUMET.
 - 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.
 - Your doctor will do blood tests to check your kidney function before and during treatment with JANUMET.

What are the possible side effects of JANUMET?

JANUMET can cause serious side effects. See "What is the most important information I should know about JANUMET?"

Common side effects when taking JANUMET include:

- stuffy or runny nose and sore throat
- upper respiratory infection
- diarrhea

- nausea and vomiting
- gas, stomach discomfort, indigestion
- weakness
- headache

Taking JANUMET with meals can help reduce the common stomach side effects of metformin that usually occur at the beginning of treatment. If you have unusual or unexpected stomach problems, talk with your doctor. Stomach problems that start up later during treatment may be a sign of something more serious.

Certain diabetes medicines, such as sulfonylureas and meglitinides, can cause low blood sugar (hypoglycemia). When JANUMET is used with these medicines, you may have blood sugars that are too low. Your doctor may prescribe lower doses of the sulfonylurea or meglitinide medicine. Tell your doctor if you are having problems with low blood sugar.

Serious allergic reactions can happen with JANUMET or sitagliptin, one of the medicines in JANUMET. Symptoms of a serious allergic reaction may include rash, hives, and swelling of the face, lips, tongue, and throat, difficulty breathing or swallowing. If you have an allergic reaction, stop taking JANUMET and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.

These are not all the possible side effects of JANUMET. For more information, ask your doctor.

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

How should I store JANUMET?

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

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

General information about the use of JANUMET

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

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

What are the ingredients in JANUMET?

Active ingredients: sitagliptin and metformin hydrochloride.

Inactive ingredients: microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, and sodium stearyl fumarate. The tablet film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black 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 problems, kidney problems, blindness, and amputation.

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

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