**Medication Guide**
**JANUMET® XR (JAN-you-met XR)**
**(sitagliptin and metformin hydrochloride extended-release)**
**Tablets**

Read this Medication Guide carefully before you start taking JANUMET XR and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about JANUMET XR, ask your doctor or pharmacist.

**What is the most important information I should know about JANUMET XR?**
**Serious side effects can happen in people taking JANUMET XR**, including:

1. **Lactic Acidosis.** Metformin, one of the medicines in JANUMET XR, can cause a rare but serious condition 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 the hospital.

   **Stop taking JANUMET XR and call your doctor right away if you get any of the following symptoms, which could be signs of lactic acidosis.**
   You:
   - feel very weak or tired.
   - have unusual (not normal) muscle pain.
   - have trouble breathing.
   - have unusual sleepiness or sleep longer than usual.
   - have sudden stomach or intestinal problems with nausea and vomiting or diarrhea.
   - feel cold, especially in your arms and legs.
   - feel dizzy or lightheaded.
   - have a slow or irregular heartbeat.

**You have a higher chance of getting lactic acidosis if you:**
- have kidney problems. People whose kidneys are not working properly should not take JANUMET XR.
- have liver problems.
- have congestive heart failure that requires treatment with medicines.
- drink alcohol very often, or drink a lot of alcohol in 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 do not drink enough fluids.
- have certain x-ray tests with dyes or contrast agents that are injected into your body.
- have surgery.
- have a heart attack, severe infection, or stroke.

2. **Pancreatitis** (inflammation of the pancreas) which may be severe and lead to death.
   Certain medical problems make you more likely to get pancreatitis.

**Before you start taking JANUMET XR:**
Tell your doctor if you have ever had
- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

Stop taking JANUMET XR and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.



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**What is JANUMET XR?**

- JANUMET XR is a prescription medicine that contains 2 prescription diabetes medicines, sitagliptin (JANUVIA®) and extended-release metformin hydrochloride. JANUMET XR can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- JANUMET XR is not for people with type 1 diabetes.
- JANUMET XR is not for people with diabetic ketoacidosis (increased ketones in your blood or urine).
- If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take JANUMET XR.
- It is not known if JANUMET XR is safe and effective when used in children under 18 years of age.

**Who should not take JANUMET XR?**
**Do not take JANUMET XR if:**

- your kidneys are not working properly.
- you are allergic to any of the ingredients in JANUMET XR. See the end of this Medication Guide for a complete list of ingredients in JANUMET XR.
  Symptoms of a serious allergic reaction to JANUMET XR may include:
  - rash
  - raised red patches on your skin (hives)
  - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing
- you have diabetic ketoacidosis. See "**What is JANUMET XR?**".

**What should I tell my doctor before taking JANUMET XR?**
**Before you take JANUMET XR, tell your doctor if you:**

- have or have had inflammation of your pancreas (pancreatitis).
- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- drink alcohol very often, or drink a lot of alcohol in short-term “binge” drinking.
- are going to get an injection of dye or contrast agents for an x-ray procedure; JANUMET XR will need to be stopped for a short time. Talk to your doctor about when you should stop JANUMET XR and when you should start JANUMET XR again. See “**What is the most important information I should know about JANUMET XR?**”.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if JANUMET XR 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.

  **Pregnancy Registry:** If you take JANUMET XR at any time during your pregnancy, talk with your doctor about how you can join the JANUMET XR pregnancy registry. The purpose of this registry is to collect information about the health of you and your baby. You can enroll in this registry by calling 1-800-986-8999.
- are breast-feeding or plan to breast-feed. It is not known if JANUMET XR will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking JANUMET XR.

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

**How should I take JANUMET XR?**

- Take JANUMET XR exactly as your doctor tells you. Your doctor will tell you how many JANUMET XR tablets to take and when you should take them.
- Your doctor may change your dose of JANUMET XR if needed.
- Your doctor may tell you to take JANUMET XR along with certain other diabetes medicines. Low blood sugar (hypoglycemia) can happen more often when JANUMET XR is taken with certain other diabetes medicines. See "**What are the possible side effects of JANUMET XR?**".
- Take JANUMET XR 1 time each day with a meal to help to lower your chance of having an upset stomach. It is better to take JANUMET XR with your evening meal.
- Swallow JANUMET XR tablets whole. Never crush, split or chew JANUMET XR tablets. Tell your doctor if you cannot swallow tablets whole.
- Continue to take JANUMET XR as long as your doctor tells you.
- If you take too much JANUMET XR, call your doctor or local 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 2 doses of JANUMET XR at the same time.
- You may need to stop taking JANUMET XR 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 get an injection of dye or contrast agent for an x-ray procedure. See "**What is the most important information I should know about JANUMET XR?**" and "**What should I tell my doctor before taking JANUMET XR?".**
- 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 problems and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking JANUMET XR.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with JANUMET XR.

**What are the possible side effects of JANUMET XR?**
**Serious side effects have happened in people taking JANUMET XR or the individual medicines in JANUMET XR.**

- See "**What is the most important information I should know about JANUMET XR?**".
- **Low blood sugar (hypoglycemia).** If you take JANUMET XR with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you use JANUMET XR. Signs and symptoms of low blood sugar may include:



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- headache
- drowsiness
- weakness
- dizziness
- confusion
- irritability
- hunger
- fast heart beat
- sweating
- feeling jittery

- **Serious allergic reactions.** If you have any symptoms of a serious allergic reaction, stop taking JANUMET XR and call your doctor right away. See "**Who should not take JANUMET XR?**". Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.
- **Kidney problems,** sometimes requiring dialysis.

The most common side effects of JANUMET XR include:

- stuffy or runny nose and sore throat
- upper respiratory infection
- diarrhea
- nausea and vomiting
- gas, upset stomach, indigestion
- weakness
- headache
- low blood sugar (hypoglycemia) when used in combination with certain medications, such as a sulfonylurea or insulin.

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

JANUMET XR may have other side effects, including:

- swelling of the hands or legs. Swelling of the hands and legs can happen if you take JANUMET XR in combination with rosiglitazone (Avandia®). Rosiglitazone is another type of diabetes medicine.

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

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store JANUMET XR?**
Store JANUMET XR at 68°F to 77°F (20°C to 25°C). Store in a dry place and keep cap tightly closed.

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

**General information about the use of JANUMET XR.**
Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use JANUMET XR for a condition for which it was not prescribed. Do not give JANUMET XR to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about JANUMET XR. If you would like to know more information, talk with your doctor. You can ask your doctor or pharmacist for additional information about JANUMET XR that is written for health care professionals. For more information go to www.janumetxr.com or call 1-800-622-4477.

**What are the ingredients in JANUMET XR?**



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**Active ingredients:** sitagliptin and metformin hydrochloride extended-release
**Inactive ingredients:**

- **All doses of JANUMET XR Tablets contain**: povidone, hypromellose, colloidal silicon dioxide, sodium stearyl fumarate, propyl gallate, polyethylene glycol, and kaolin. Film coating contains hypromellose, hydroxypropyl cellulose, titanium dioxide, FD&C #2/Indigo Carmine Aluminum Lake and carnauba wax.
- **In addition the JANUMET XR 50 mg/500 mg Tablets also contain:** microcrystalline cellulose.
- **In addition the JANUMET XR 50 mg/1000 mg Tablets also contain:** 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.
High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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