

JANUMET[®] XR FILM-COATED TABLETS

Sitagliptin Phosphate/ Metformin Hydrochloride (50mg/500mg, 50mg/1000mg, 100mg/1000mg)

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What JANUMET XR is used for

JANUMET is a tablet that contains two prescription medicines, sitagliptin phosphate (JANUVIA[™]) and metformin, which lower blood sugar. Sitagliptin, a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin, a member of the biguanide class of medicines, work together to control blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM

Your doctor has prescribed JANUMET XR, along with diet and exercise, to help lower your blood sugar.

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 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.

How JANUMET XR works

- JANUMET XR lowers blood sugar levels in patients with type 2 diabetes.
- JANUMET XR helps to improve the levels of insulin after a meal.
- JANUMET XR helps the body respond better to the insulin it makes naturally.
- JANUMET XR decreases the amount of sugar made by the body.
- JANUMET XR is unlikely to cause low blood sugar (hypoglycemia).

Before you use JANUMET XR

- When you must not use it

You should not take JANUMET XR if you:

- have type 1 diabetes.
- have severely reduced kidney function.
- are allergic to sitagliptin (JANUVIA[™]), metformin hydrochloride, or any other components of JANUMET XR. See “**Product Description, Ingredients**” for a complete list of all ingredients in JANUMET XR.
- have lactic acidosis [too much lactic acid in the blood (see “Risk of lactic acidosis” below)] or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms of acidosis may

include stomach pain, abnormal breathing and drowsiness (if severe).

- are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your doctor about when to stop JANUMET XR and when to start again.

- Before you start to use it

You should tell your doctor if you:

- have severe kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- drink alcohol a lot (all the time or short-term “binge” drinking).
- have ever had gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis.

Risk of lactic acidosis

JANUMET XR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking JANUMET XR for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea, fever, exposure to heat or if you drink less fluid

than normal. Talk to your doctor for further instructions.

Stop taking JANUMET XR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with JANUMET XR, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Use in children

JANUMET XR is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. JANUMET XR has not been studied in children younger than 10 years of age.

- Taking other medicines

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

In particular, tell your doctor:

- if you are taking digoxin (a medicine used to treat

irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with JANUMET XR.

How to use JANUMET XR

- How much to use

- Use JANUMET XR exactly as your doctor has prescribed. Your doctor will tell you how many JANUMET XR tablets to take and how often you should take them.
- Your doctor may prescribe JANUMET XR along with a sulfonylurea, a glitazone or insulin (other medicines to lower blood sugar).

- When to use it

- Use JANUMET XR once a day with food preferably in the evening to lower your chance of an upset stomach.
- If you use JANUMET XR, swallow the JANUMET XR tablets whole. Do not chew, cut, or crush the tablets.
- You may see something that looks like the JANUMET XR tablet in your stool. If you see tablets in your stool several times, talk to your doctor. Do not stop taking JANUMET XR without talking to your doctor.

- How long to use it

- Continue to use JANUMET XR as long as your doctor prescribes it so you can continue to help control your blood sugar.

- If you forget to use it

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 JANUMET XR.

- If you use too much (overdose)

If you take too much JANUMET XR, call your doctor or visit the Emergency Department of the hospital near you right away.

While you are using JANUMET XR

- Things you must do

You may need to stop JANUMET XR for a short time. Call your doctor for instructions if you:

- have a condition that may be associated with dehydration (large loss of body fluids) such as being sick with severe vomiting, diarrhea or fever, or if you drink fluids a lot less than normal.
- plan to have surgery.
- are going to get or receive an injection of dye or contrast agent for an x-ray procedure.

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving JANUMET XR. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking JANUMET XR and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving JANUMET XR. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking JANUMET XR.

- Things you must not do

Do not take Janumet XR if you plan to become pregnant or during pregnancy without consulting your doctor.

Do not take Janumet XR if you are breast-feeding or plan to breast-feed.

- Things you must be careful of

Do not drive or operate machinery until you know how Janumet XR affects you.

Janumet XR should be used with caution as age increases, especially in elderly. Your doctor will carefully select the dose and regularly monitoring your kidney function.

Side effects

In rare cases, metformin, one of the medicines in JANUMET XR, can cause a serious side effect called lactic acidosis. Lactic acidosis is a medical emergency that can cause death and must be treated in the hospital. Lactic acidosis is caused by a build-up of lactic acid in your blood.

Stop using JANUMET XR if you get 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 stomach pain 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.
- Your medical condition suddenly changes.

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

- have severe 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 used.
- have surgery.
- have a heart attack, severe infection, or stroke.

Very common side effects in patients taking Metformin XR alone include (may affect more than 1 in 10 people):

- digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Common side effects in patients taking Metformin XR alone include (may affect up to 1 in 10 people):

- changes in taste.
- Decreased or low vitamin B₁₂ levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare side effects in patients taking Metformin XR alone include (may affect up to 1 in 10,000 people):

- abnormalities in liver function tests or hepatitis

(inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, stop taking JANUMET XR and talk to your doctor.

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

Common side effects in patients taking sitagliptin alone include stuffy or running nose and sore throat, upper respiratory tract infection, and headache.

Side effects seen in clinical trials using the combination of sitagliptin and metformin (the medicines in JANUMET XR) were generally similar to metformin taken alone. Taking JANUMET XR with meals can help reduce stomach side effects. However, if you have unusual and/or unexpected stomach problems, talk with your doctor. Stomach problems that start up later during treatment may be a sign of something more serious.

When JANUMET XR is used with a sulfonylurea medicine or with insulin, low blood sugar (hypoglycemia), due to the sulfonylurea or insulin, can occur. Lower doses of the sulfonylurea medicine or insulin may be required. In addition, when JANUMET XR is used with a sulfonylurea medicine, constipation may occur.

When JANUMET XR was used in combination with rosiglitazone (a glitazone medicine), the following side effects were reported: headache, low blood sugar (hypoglycemia), diarrhea, upper respiratory infection, nausea, cough, fungal skin infection, swelling of the hands or legs, and vomiting.

Additional side effects have been reported in general use with JANUMET XR, or sitagliptin, one of the medicines in JANUMET XR. These side effects have been reported when JANUMET XR, or sitagliptin have been used by themselves and/or with other diabetes medicines:

- 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 JANUMET XR and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.
- Inflammation of the pancreas.
- Kidney problems (sometimes requiring dialysis).
- Constipation.
- Vomiting.
- Joint pain.
- Muscle aches.
- Arm or leg pain.
- Back pain.
- Itching
- Blisters.
- Reduced number of platelets.

Other side effects not listed above may also occur in some patients.

Tell your doctor or pharmacist if you develop any unusual side effect, or if any known side effect does not go away or gets worse.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of JANUMET XR

- Storage

Store below 30°C (86°F). Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- What it looks like

JANUMET XR 50mg/500mg: Light blue, bi-convex oval, film coated tablet, debossed “78” on one side and plain on the other. It is available in trade packs of 56’s.

JANUMET XR 50mg/1000mg: Light green, bi-convex oval, film coated tablet, debossed “80” on one side and plain on the other. It is available in trade packs of 56’s.

JANUMET XR 100mg/1000mg: Blue, bi-convex oval, film coated tablet, debossed “81” on one side and plain on the other. It is available in trade packs of 28’s.

- Ingredients

Active ingredient:

JANUMET XR is a tablet that contains sitagliptin and metformin hydrochloride extended-release as active ingredients.

- JANUMET XR 50mg sitagliptin phosphate/500mg metformin hydrochloride extended-release

- JANUMET XR 50mg sitagliptin phosphate/1000mg metformin hydrochloride extended-release

- JANUMET XR 100mg sitagliptin phosphate/1000mg metformin hydrochloride extended-release

Inactive ingredients:

All doses of JANUMET XR contain the following inactive ingredients: povidone, hypromellose, colloidal silicon dioxide, sodium stearyl fumarate, propyl gallate, microcrystalline cellulose (Janumet XR 50/500mg only), polyethylene glycol, and kaolin.

The film coating contains the following inactive ingredients: hypromellose, hydroxypropyl cellulose, titanium dioxide, FD&C Blue #2/Indigo Carmine Aluminum Lake, yellow iron oxide (Janumet XR 50/1000mg only) and carnauba wax.

- MAL numbers

JANUMET XR 50mg/500mg:
MAL14125082ACRZ

JANUMET XR 50mg/1000mg:
MAL14125083ACRZ

JANUMET XR 100mg/1000mg:
MAL14125081ACRZ

Manufacturer

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Product Registration Holder

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