

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

 **JANUMET®**

sitagliptin and metformin hydrochloride tablets

 **JANUMET® XR**

sitagliptin and metformin hydrochloride extended-release tablets

Read this carefully before you start taking **JANUMET®** or **JANUMET® XR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JANUMET®** and **JANUMET® XR**.

Serious Warnings and Precautions

Lactic acidosis is a rare but serious buildup of acid in the blood. It can cause death. It must be treated in the hospital. **JANUMET®** and **JANUMET® XR** contain the medicinal ingredient metformin hydrochloride. If you build up too much metformin in your blood you are at risk for lactic acidosis.

Alcohol increases the risk of lactic acidosis caused by metformin. Do not “binge” drink or drink alcohol often when you are taking **JANUMET®** or **JANUMET® XR**.

What are **JANUMET®/JANUMET® XR** used for?

JANUMET® and **JANUMET® XR** are used in addition to diet and exercise to improve blood sugar levels in adult patients with type 2 diabetes mellitus:

- alone, in patients who are not controlled on metformin alone or currently on sitagliptin and metformin.
- in combination with a sulfonylurea, in patients who are not controlled on metformin and a sulfonylurea.
- in combination with premixed or long/intermediate acting insulin.
- in combination with pioglitazone, in patients who are not controlled on metformin and pioglitazone.

How does **JANUMET®/JANUMET® XR** work?

JANUMET® and **JANUMET® XR** contain the medicinal ingredients sitagliptin and metformin. These two medicines work together to help you achieve better blood sugar control.

Sitagliptin is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Sitagliptin helps to improve the levels of insulin when blood sugar level is high, especially

after a meal. Sitagliptin also helps to decrease the amount of sugar made by the body. Sitagliptin is unlikely to cause low blood sugar (**hypoglycemia**).

Metformin is a member of the biguanide class of medicines, it helps to lower the amount of sugar made by the liver.

What are the ingredients in JANUMET®/JANUMET® XR?

- Medicinal ingredients: Sitagliptin phosphate monohydrate and metformin hydrochloride
- Non-medicinal ingredients:
 - **JANUMET®**: black iron oxide, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, red iron oxide, sodium lauryl sulfate, sodium stearyl fumarate, talc and titanium dioxide.
 - **JANUMET® XR**: carnauba wax, colloidal silicon dioxide, FD&C Blue #2/Indigo Carmine Aluminum Lake, hydroxypropyl cellulose, hypromellose, kaolin, microcrystalline cellulose (50 mg/500 mg tablet), polyethylene glycol, povidone, propyl gallate, sodium stearyl fumarate, titanium dioxide and yellow iron oxide (50 mg/1000 mg tablet).

JANUMET®/JANUMET® XR comes in the following dosage forms:

JANUMET® tablets contain sitagliptin (as sitagliptin phosphate monohydrate)/metformin hydrochloride 50 mg/500 mg, 50 mg/850 mg, or 50 mg/1000 mg.

JANUMET® XR tablets contain immediate release sitagliptin (as sitagliptin phosphate monohydrate) /extended-release metformin hydrochloride 50 mg/500 mg, 50 mg/1000 mg or 100 mg/1000 mg.

Do not use JANUMET®/JANUMET® XR if you:

- are allergic (hypersensitive) to sitagliptin, metformin, or any of the other ingredients in JANUMET® or JANUMET® XR.
- have unstable and/or insulin-dependent (type 1) diabetes mellitus.
- have metabolic acidosis (including diabetic ketoacidosis, history or ketoacidosis or lactic acidosis – too much acid in the blood).
- have severe kidney disease.
- have liver problems.
- drink alcohol very often or drink a lot of alcohol in the short term (“binge” drinking).
- have severe heart problems or heart failure.
- have a lack of oxygen in the blood. This is called hypoxemia. This can happen when you have conditions that affect your heart or breathing.
- are stressed, have severe infections, are experiencing trauma, are about to have surgery, or are recovering from surgery.
- have severe **dehydration** (have lost a lot of water from your body) or shock.
- are breastfeeding.
- are pregnant or planning to become pregnant.
- are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your healthcare professional about when to stop JANUMET® or JANUMET® XR and when to start again.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JANUMET®/JANUMET® XR. Talk about any health conditions or problems you may have,

including if you:

- are older than 65 years of age;
- have or have had pancreatitis (inflammation of the pancreas);
- have risk factors for pancreatitis such as:
 - gallstones (solid particles that form in the gall bladder),
 - a history of alcoholism,
 - high triglyceride levels;
- have heart problems including congestive heart failure (a condition where your heart becomes weaker and less able to pump the blood that your body needs);
- have or have had severe kidney problems;
- have liver problems;
- had an organ transplant;
- have human immunodeficiency syndrome (HIV);
- have vitamin B₁₂ deficiency or anemia;
- have hypothyroidism (low levels of thyroid hormones).

Other warnings you should know about:

Lactic Acidosis (high levels of lactic acid in your blood):

- **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 **dehydration** (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. Tell your healthcare professional if this happens;
 - have certain x-ray tests with injectable dyes or contrast agents used. Tell your healthcare professional if you are going to have these types of tests. JANUMET® and JANUMET® XR are usually stopped before the test and for two days after;
 - have surgery. Talk with your healthcare professional before any surgery if you must restrict what you eat and drink. In these cases, JANUMET® or JANUMET® XR should be stopped for 2 days before the surgery. Wait until you are eating and drinking again before you restart JANUMET® or JANUMET® XR;
 - have a heart attack, severe infection, or stroke;
 - take other medications.

Serious Skin Reactions and Pancreatitis:

- **JANUMET® and JANUMET® XR can cause serious side effects, including:**
 - **Pancreatitis** (inflammation of the pancreas) which can be life-threatening and cause death.
 - **Serious Skin Reactions** called **Stevens-Johnson syndrome** and **bullous pemphigoid**. These reactions can happen after your first dose or up to 3 months after you start taking JANUMET® or JANUMET® XR.

See the **Serious side effects and what to do about them** table, below for more information on these and other serious side effects.

Hypoglycemia (low blood sugar):

- When JANUMET® or JANUMET® XR is used with a sulfonylurea medicine or with insulin, **hypoglycemia** (low blood sugar) can occur. Lower doses of the sulfonylurea medicine or insulin may be required while you take JANUMET® or JANUMET® XR. You should use caution when driving or using machines if you are taking JANUMET® or JANUMET® XR with a sulfonylurea medicine or with insulin.

Blood Tests:

- JANUMET® and JANUMET® XR may cause abnormal blood tests. Your healthcare professional will do blood tests before you start JANUMET® or JANUMET® XR and while you are taking it. They may check your blood sugar, liver and thyroid function, vitamin B₁₂ levels and how well your kidneys are working. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

If you start any new medicine, tell your healthcare professional.

The following may interact with JANUMET® or JANUMET® XR:

- Other diabetes medicines such as glyburide.
- Furosemide, used to treat heart failure.
- Nifedipine, used to treat high blood pressure and chest pain.
- Ranolazine, used to treat chest pain.
- Vandetanib, used to treat thyroid cancer.
- Dolutegravir, used to treat HIV infection and AIDS.
- Cimetidine, used to treat stomach problems.
- Certain “blood thinners” used to prevent blood clots, such as phenprocoumon or other antivitamin K anticoagulants.
- Other medicines that tend to produce high blood sugar (hyperglycemia) and may lead to a loss of blood sugar control. Some examples include:
 - Thiazide and other diuretics (water pills), used to treat high blood pressure
 - Corticosteroids, used to treat joint pain and swelling
 - Phenothiazines, used to treat schizophrenia
 - Thyroid products
 - Estrogens or estrogens plus progestogen
 - Oral contraceptives (birth control pills)
 - Phenytoin, used to treat epilepsy
 - Nicotinic acid, used to treat high cholesterol
 - Sympathomimetics, used for heart problems
 - Calcium channel blockers, used to treat high blood pressure
 - Isoniazid, used to treat tuberculosis
 - Beta-2-agonists, used to treat breathing problems
 - Carbonic anhydrase inhibitors, used to treat glaucoma, heart failure, epilepsy and other conditions
- ACE inhibitors, used to treat high blood pressure, may lower blood glucose and the combination with JANUMET® or JANUMET® XR should be carefully monitored.

How to take JANUMET® or JANUMET® XR:

- Take JANUMET® or JANUMET® XR exactly as your healthcare professional tells you to. Your healthcare professional will decide on the dose that is right for you based on the medicines you are currently taking. Do not stop taking JANUMET® or JANUMET® XR or change your dose without talking to your healthcare professional.
- Your healthcare professional may change your dose based on your blood sugar levels.
- Take JANUMET® and JANUMET® XR with food to avoid stomach upset.
- JANUMET® XR tablets are to be swallowed whole. Do **not** chew, cut, or crush the JANUMET® XR tablets.
- You may see something that looks like the JANUMET® XR tablet in your stool (bowel movement). If this happens, check your blood sugar. If your blood sugar control has changed, tell your healthcare professional.

Usual adult dose:

JANUMET®: One tablet, 2 times a day.

JANUMET® XR: Take your tablet(s) once a day preferably in the evening.

Overdose:

If you think you, or the person you are caring for, have taken too much JANUMET® or JANUMET® XR, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

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® or JANUMET® XR at the same time to make up for a missed dose.

What are possible side effects from using JANUMET® or JANUMET® XR?

These are not all the possible side effects that you may have when taking JANUMET® or JANUMET® XR. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Arm or leg pain
- Back pain
- Blisters
- Gastrointestinal symptoms: diarrhea, constipation, nausea, vomiting, abdominal bloating, upset stomach, gas and loss of appetite
- Headache
- Itching
- Joint pain
- Muscle aches
- Sore throat

- Stuffy or runny nose

Serious side effects and what to do about them			
Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hypoglycemia (low blood sugar - when used with a sulfonylurea or with insulin): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		X	
RARE			
Pancreatitis (inflammation of the pancreas): prolonged severe stomach pain and possible vomiting.			X
Allergic reactions: rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			X
Serious skin reactions including Stevens-Johnson syndrome, bullous pemphigoid: blisters or breakdown of your skin.		X	
Lactic acidosis (buildup of lactic acid in the blood): malaise or a feeling of general discomfort, uneasiness or pain; feeling very weak or tired; sleepiness, drowsiness or an increasing strong desire for sleep; low blood pressure, dizziness, lightheadedness; cold hands or feet; slow or irregular heartbeat, trouble breathing; unusual muscle pain; stomach pain with nausea, vomiting, or diarrhea.			X
Encephalopathy (disease of the brain that severely alters thinking): muscle weakness in one area, poor decision-making or concentration, involuntary twitching, trembling, difficulty speaking or swallowing, seizures.			X
Thyroid problems in patients with low thyroid function: fatigue, feeling cold, dry skin, poor memory and concentration, weight gain.		X	
Acute kidney failure (sometimes requiring dialysis): nausea, loss of appetite and weakness, pass little or no urine, breathlessness.			X

Serious side effects and what to do about them			
Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hemolytic anemia (when red blood cells are destroyed faster than bone marrow can replace them): fatigue, pale color, rapid heartbeat, shortness of breath, dark urine, chills, and backache.			X
Peripheral neuropathy (damage to the nerves in your arms or legs): gradual onset of numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms, sharp, jabbing, throbbing, freezing or burning pain, extreme sensitivity to touch, lack of coordination and falling, muscle weakness or paralysis if motor nerves are affected.			X
VERY RARE			
Vitamin B₁₂ deficiency (decreased vitamin B₁₂ levels in the blood): fatigue, shortness of breath, tingling or numbness of the fingers or toes, difficulty walking properly, irritability, confusion, tender calves.		X	
Liver problems: yellow of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		X	
Rhabdomyolysis (breakdown of damaged muscle): muscle spasms, weakness, red-brown (tea-coloured) urine.			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

JANUMET® should be stored at 15°C to 25°C.

JANUMET® XR should be stored at 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about JANUMET®/JANUMET® XR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html> or the Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

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