

JANUMET® XR

Sitagliptin phosphate monohydrate/metformin hydrochloride modified release

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about JANUMET XR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking JANUMET XR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What JANUMET XR is used for

JANUMET XR helps to lower blood sugar levels in patients with type 2 diabetes mellitus along with diet and exercise. JANUMET XR can be used alone, or in combination with ertugliflozin, insulin, or sulfonylurea medicines such as glimepiride, gliclazide and glibenclamide.

Type 2 diabetes mellitus

Type 2 diabetes mellitus 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 resulting in high blood sugar (hyperglycaemia). 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 foot amputation.

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

How JANUMET XR works

JANUMET XR contains two active ingredients, sitagliptin (as phosphate monohydrate) and metformin hydrochloride.

Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin belongs to a class of medicines called biguanides.

Sitagliptin and metformin work together to control blood sugar levels in patients with type 2 diabetes mellitus.

- JANUMET XR helps to improve the levels of insulin after a meal.
- JANUMET XR decreases the amount of sugar made by the body.
- JANUMET XR works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. JANUMET XR also lowers blood sugar between meals.

Before you take JANUMET XR

When you must not take it

Do not take JANUMET XR if:

- **you have an allergy to sitagliptin or metformin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.

- **the packaging is torn or shows signs of tampering.**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking JANUMET XR, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant.**

JANUMET XR is not recommended for use during pregnancy.

2. **you are breastfeeding or plan to breastfeed.**

JANUMET XR should not be used while breastfeeding or if planning to breastfeed.

3. **you have or have had type 1 diabetes mellitus or a condition called diabetic ketoacidosis (increased ketones in the blood or urine).**

JANUMET XR should not be used for the treatment of these conditions.

4. you have severe kidney problems

JANUMET XR should not be used in individuals with severe kidney problems.

5. you have any liver or heart problems including congestive heart failure or any past or present medical problems.

JANUMET XR should not be used in individuals with certain liver or heart problems.

6. you have or have had an allergic reaction to sitagliptin (JANUVIA), metformin, JANUMET or JANUMET XR, or you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

7. you drink excessive alcohol (all the time or short term "binge" drinking).

8. you are going to get or receive an injection of dye or contrast agent for an X-ray procedure, or if you plan to have surgery.

Talk to your doctor about when to stop JANUMET XR and when to start again.

If you have not told your doctor about any of the above, tell him/her before you take any JANUMET XR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines and herbal supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

JANUMET XR may affect how well other drugs work and some drugs can affect how well JANUMET XR works.

How to take JANUMET XR

Take JANUMET XR only when prescribed by your doctor.

Your doctor will tell you how many JANUMET XR tablets to take.

JANUMET XR tablets should be taken once a day.

Take JANUMET XR with meals to lower your chance of an upset stomach.

Swallow JANUMET XR tablets whole with a glass of water. Do not chew, cut, or crush the tablets. Tell your doctor if you cannot swallow JANUMET XR whole.

You may see something that looks like the JANUMET XR tablet in your stool (bowel movement). If you see tablets in your stool several times, talk to your doctor. Do not stop taking JANUMET XR without talking to your doctor.

Follow all directions given to you by your doctor and pharmacist carefully.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How long to take it

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

Make sure you keep enough JANUMET XR to last over weekends and holidays.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor's recommended diet, exercise and weight loss program while taking JANUMET XR.

If you forget to take 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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose of JANUMET XR to make up for the dose that you missed.

If you have trouble remembering to take your tablet, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand: 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much JANUMET XR. Do this even if there are no signs of discomfort or poisoning.

If you take too much JANUMET XR, you may feel sick, vomit, have trouble breathing and have stomach pain or diarrhoea. These may be the early signs of a serious condition called lactic acidosis.

If you experience any of these symptoms, immediately get medical help.

While you are using JANUMET XR

Things you must do

If you become pregnant while taking JANUMET XR, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking JANUMET XR.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

HYPOGLYCAEMIA

JANUMET XR does not normally cause hypoglycaemia, although you

may experience it if you take certain other medicines.

When JANUMET XR is used with insulin, low blood sugar (hypoglycaemia) due to the insulin, can occur. Lower doses of insulin may be required.

Signs of hypoglycaemia may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness

At the first signs of hypoglycaemia, you need to raise your blood glucose quickly.

You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you notice the return of any signs of hyperglycaemia, contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress

- taking less JANUMET XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated, such as being sick with severe vomiting, diarrhoea or if you drink fluids a lot less than normal
- are injured
- have a fever
- have a serious infection
- plan to have surgery

Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace JANUMET XR with insulin.

Make sure you check your blood glucose levels regularly.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

See your doctor once a year for a check on your body's level of vitamin B12.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Things you must not do

Do not give JANUMET XR to anyone else, even if they have the same condition as you.

Do not stop taking JANUMET XR or change your dose without checking with your doctor.

Things to be careful of

The effect of JANUMET XR on the ability to drive a car or operate machinery has not been studied, although it is thought to be unlikely to have any effect on these activities.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking JANUMET XR.

Like all prescription medicines, JANUMET XR may cause side effects. In studies, side effects were usually mild and did not cause patients to stop taking JANUMET XR.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- signs of an infection of the breathing passages, including runny nose, sore throat, cough
- upper respiratory tract infection
- nausea and vomiting
- headache
- diarrhoea
- indigestion, wind, uncomfortable feeling in the stomach
- 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.

Tell your doctor immediately or go to the accident and emergency at your nearest hospital if you notice any of the following:

- 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.

- Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking JANUMET XR and call your doctor right away if you experience these symptoms.

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, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

STOP TAKING JANUMET XR IF YOU GET ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS AND SEE YOUR DOCTOR IMMEDIATELY:

- 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 diarrhoea.

- 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.

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:

- Kidney problems (sometimes requiring dialysis)
- Constipation
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

Common side effects in patients taking metformin alone include diarrhoea, nausea/vomiting, flatulence, weakness, indigestion, abdominal discomfort and headache. Diarrhoea and nausea/vomiting were seen in patients treated with modified-release metformin products.

Tell your doctor if you notice any other effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using JANUMET XR

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep JANUMET XR in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking JANUMET XR or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

JANUMET XR comes as three strengths of tablets:

- 50 mg/500 mg tablet*: A light blue, bi-convex oval, film coated tablet, with "78" on one side and plain on the other. Available in packs of 14 tablets (starter pack), and 56 tablets.
- 50 mg/1000 mg tablet: A light green, bi-convex oval, film coated tablet, with "80" on one side and plain on the other. Available in packs of 14 tablets (starter pack), and 56 tablets.
- 100 mg/1000 mg - A blue, bi-convex oval, film coated tablet, with "81" on one side and plain on the other. Available in packs of 7 tablets (starter pack), and 28 tablets.

*Presentation not currently marketed in Australia.

Ingredients

Active ingredients:

- Sitagliptin 50 or 100 mg per tablet (as free base)

- Metformin 500 or 1000 mg

Inactive ingredients:

- Povidone
- Hypromellose
- Silica - colloidal anhydrous
- Sodium stearyl fumarate
- Propyl gallate
- Macrogol 3350
- Kaolin

The JANUMET XR 50 mg/500 mg tablet contains the additional inactive ingredient microcrystalline cellulose.

Ingredients of film-coating:

- Hypromellose
- Hydroxypropylcellulose
- Titanium dioxide
- Indigo Carmine
- Carnauba wax

The JANUMET XR 50 mg/1000 mg tablet contains the additional inactive ingredient iron oxide yellow.

JANUMET XR does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

JANUMET XR is supplied in Australia by:

Merck Sharp & Dohme (Australia)
Pty Limited
Level 1, Building A,
26 Talavera Road
MACQUARIE PARK NSW 2113

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