JANUMET XR®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking JANUMET XR?

JANUMET XR contains the active ingredients sitagliptin (as phosphate monohydrate) and metformin (as hydrochloride). JANUMET XR is used to lower blood sugar levels in adults with type 2 diabetes mellitus.

For more information, see Section 1. Why am I taking JANUMET XR? in the full CMI.

2. What should I know before I take JANUMET XR?

Do not use if you have ever had an allergic reaction to JANUMET XR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take JANUMET XR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with JANUMET XR and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take JANUMET XR?

- Take your JANUMET XR tablets once a day with a meal.

More instructions can be found in Section 4. How do I take JANUMET XR? in the full CMI.

5. What should I know while taking JANUMET XR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking JANUMET XR. • Call your doctor straight away if you if you become pregnant while taking JANUMET XR.
Things you should not do	• Do not stop taking this medicine suddenly. • Do not give JANUMET XR to anyone else, even if they have the same condition as you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your tablets in the bottle until it is time to take them. • Store JANUMET XR in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using JANUMET XR? in the full CMI.

6. Are there any side effects?

Serious side effects in particular that need to be noted are:

- Allergic reactions including rash, hives, swelling of the face, lips, tongue, and throat with difficulty in breathing or swallowing.
- Severe and persistent stomach pain, often with nausea and vomiting.
- Blisters or the breakdown of your skin (erosion).
- Low blood sugar when used in combination with a sulfonylurea medicine or with insulin.
- Kidney problems (sometimes requiring dialysis).
- Thyroid problems in patients with low thyroid function including fatigue, feeling cold, dry skin, poor memory and concentration, weight gain

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

JANUMET XR

Active ingredient(s): *Sitagliptin (as phosphate monohydrate)/Metformin (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking JANUMET XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking JANUMET XR.**

Keep this leaflet with the medicine.

You may need to read it again.

Where to find information in this leaflet:

1. Why am I taking JANUMET XR?
2. What should I know before I take JANUMET XR?
3. What if I am taking other medicines?
4. How do I use JANUMET XR?
5. What should I know while taking JANUMET XR?
6. Are there any side effects?
7. Product details

1. Why am I taking JANUMET XR?

JANUMET XR contains two active ingredients: sitagliptin and metformin. Sitagliptin is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin which belongs to a class of medicines called biguanides. Sitagliptin and metformin work together to control blood sugar levels in adults with type 2 diabetes mellitus.

JANUMET XR is used to lower blood sugar levels in adults with type 2 diabetes mellitus along with diet and exercise. JANUMET XR can be used alone or in combination with certain other medicines that lower blood sugar along with a recommended diet and exercise program.

2. What should I know before I take JANUMET XR?

Warnings

Do not take JANUMET XR if:

- you are allergic to sitagliptin or metformin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have or have had type 1 diabetes mellitus or
- have or have had increased ketones in the blood or urine (diabetic ketoacidosis).
- are known to suffer from a genetically inherited disease affecting mitochondria (the energy producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic Acidosis and Stroke-like episodes) or Maternal Inherited Diabetes and Deafness (MIDD).
- have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g., pain or numbness), migraine and deafness.
- have or have had severe kidney problems
- you have any liver or heart problems including congestive heart failure, or any past or present medical problems.
- drink excessive alcohol (all the time or short term "binge" drinking).
- 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.
- have hypothyroidism (low levels of thyroid hormones).
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. JANUMET XR is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not take JANUMET XR while breastfeeding or if planning to breastfeed.

Children

Children and adolescents below 18 years should not use this medicine. 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or 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.

Medicines that may cause low blood sugar when used in combination with JANUMET XR include:

- Sulfonylureas
- Insulin

A reduction in the amount of the sulfonylurea or insulin may be required.

Other medicines that tend to produce high blood sugar (hyperglycaemia) and may lead to a loss of blood sugar control. Some examples include:

- Thyroid products

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JANUMET XR.

4. How do I take JANUMET XR?

How much to take

- Your doctor will tell you how many JANUMET XR tablets to take.
- Take your JANUMET XR tablets once a day with a meal 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.

When to take JANUMET XR

- Take your JANUMET XR at about the same time each day.

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.

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.

If you forget to take JANUMET XR

JANUMET XR should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much JANUMET XR

If you think that you have taken too much JANUMET XR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while taking JANUMET XR?

Things you should do

Call your doctor straight away if you:

- Become pregnant while taking JANUMET XR, or

Tell your doctor if you:

- Become ill
- Become dehydrated
- 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.

Low blood sugar or high blood sugar

Make sure that you, your friends, family and work colleagues can recognise the symptoms of low blood sugar and high blood sugar and know how to treat them.

Low blood sugar

Signs of low blood sugar 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 low blood sugar, 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.

High blood sugar

If you notice any signs of high blood sugar, contact your doctor immediately.

The risk of high blood sugar is increased with:

- uncontrolled diabetes
- illness, infection or stress
- taking less JANUMET XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Your blood sugar 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.

Stop taking JANUMET XR if you have symptoms of lactic acidosis, such as feeling very weak and tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea and vomiting, or diarrhoea, feeling cold, especially in your arms and legs, feeling dizzy or lightheaded, a slow or irregular heart beat or your medical condition suddenly changes.

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.

Make sure you check your blood sugar levels regularly.

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

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

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

Remind any doctor, dentist or pharmacist you visit that you are taking JANUMET XR.

Things you should not do

- Do not stop taking this medicine or change your dose without checking with your doctor.
- Do not skip meals while taking JANUMET XR.
- Do not give JANUMET XR to anyone else, even if they have the same condition as you.

Driving or using machines

There is no information to suggest that JANUMET XR affects your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Signs of an infection of the breathing passages including runny nose, sore throat, cough, soreness in the back of the nose and throat and discomfort when swallowing, headache, flu-like symptoms • stomach discomfort and vomiting, diarrhoea or constipation. • Muscle aches or pain in the joints, back, arm, or leg • Itching or blisters	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Allergic reactions including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. • 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. • Kidney problems (sometimes requiring dialysis) • Low blood sugar when JANUMET XR is used in combination with a sulfonylurea medicine or with insulin. • Itching or blisters or the breakdown of your skin (erosion).	**Stop taking JANUMET XR. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Thyroid problems in patients with low thyroid function including fatigue, feeling cold, dry skin, poor memory and concentration, weight gain	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What JANUMET XR contains

Active ingredient (main ingredient)	Sitagliptin 50 or 100 mg and metformin 500 or 1000 mg per tablet
Other ingredients (inactive ingredients)	Povidone Hypromellose Silica - colloidal anhydrous Sodium stearylfumarate Propyl gallate Macrogol 3350 Kaolin JANUMET XR 50/500 also contains Microcrystalline cellulose Hydroxypropylcellulose Titanium dioxide Indigo Carmine Carnauba wax JANUMET XR 50 mg/1000 mg also contains iron oxide yellow.

Do not take this medicine if you are allergic to any of these ingredients.

What JANUMET XR looks like

JANUMET XR 50mg/500 mg is a light blue, bi-convex oval, film coated tablet, with "78" on one side and plain on the other (AUST R 205316). * not currently marketed.

JANUMET XR 50 mg/1000 mg is a light green, bi-convex oval, film coated tablet, with "80" on one side and plain on the other (AUST R 205317).

JANUMET XR 100 mg/1000 mg is a blue, bi-convex oval, film coated tablet, with "81" on one side and plain on the other (AUST R 205318).

Who distributes JANUMET XR

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

www.msdinfo.com.au/janumetxrcmi

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