

PATIENT INFORMATION LEAFLET

Information for the patient about JANUMET®

Please read this information carefully before you start to take JANUMET.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or pharmacist.
- JANUMET has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

JANUMET® 50 mg/500 mg Tablets

JANUMET® 50 mg/850 mg Tablets

JANUMET® 50 mg/1 000 mg Tablets

WHAT JANUMET CONTAINS

The active substance is:

JANUMET (sitagliptin phosphate/metformin hydrochloride) is a tablet that contains sitagliptin and metformin hydrochloride as active ingredients:

JANUMET 50 mg/500 mg: Each tablet contains 50 mg sitagliptin as phosphate and 500 mg metformin hydrochloride.

JANUMET 50 mg/850 mg: Each tablet contains 50 mg sitagliptin as phosphate and 850 mg metformin hydrochloride.

JANUMET 50 mg/1 000 mg: Each tablet contains 50 mg sitagliptin as phosphate and 1 000 mg metformin hydrochloride.

JANUMET is sugar free.

The other ingredients are: Microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulphate and sodium stearyl fumarate.

In addition, the film-coating contains the following inactive ingredients: Polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide and black iron oxide.

WHAT JANUMET IS USED FOR

JANUMET is a tablet that contains two prescription medicines, sitagliptin phosphate and metformin, which lower blood sugar levels. 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.

Why has my doctor prescribed JANUMET?

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

BEFORE YOU TAKE JANUMET

Do not take JANUMET if you:

- have type 1 diabetes
- have certain kidney problems

- have a heart problem called congestive heart failure that is treated with medicines
- are allergic to sitagliptin, metformin hydrochloride or any other components of JANUMET
- 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 and when to start again.

- are pregnant or planning to become pregnant.

Take special care with JANUMET

There are some things your doctor should know before you get this medicine.

You should tell your doctor if you:

- have kidney problems
- have liver problems
- have heart problems
- are older than 80 years. Patients over 80 years should not take JANUMET unless their kidney function is checked and it is normal.
- drink alcohol a lot (all the time or short-term “binge” drinking)
- have or have had an allergic reaction to sitagliptin, metformin, or JANUMET
- are taking any prescription medicines
- are taking non-prescription medicines
- are taking any herbal supplements.

While taking JANUMET

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

Use in children

JANUMET has not been studied in children under 18 years of age.

Use in the elderly

JANUMET should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

Taking JANUMET with food and drink

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

Pregnancy and Breastfeeding

If you are pregnant, planning to become pregnant or breastfeeding your baby, you should not take JANUMET.

It is not known if JANUMET passes into human breast milk. You should not take JANUMET if you are breastfeeding or plan to breastfeed.

Driving and using machinery

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

Taking other medicines with JANUMET

If you are taking other medicines on a regular basis including complementary and traditional medicines, concomitant use of JANUMET may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and herbal supplements.

HOW TO TAKE JANUMET

Do not share JANUMET prescribed for you with others.

Always take JANUMET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of JANUMET is too strong or too weak, talk to your doctor or pharmacist.

- Take JANUMET exactly as your doctor has prescribed. Your doctor will tell you how many JANUMET tablets to take and how often you should take them.
- Your doctor may need to increase your dose to control your blood sugar levels.
- Your doctor may prescribe JANUMET along with a sulphonylurea (another medicine to lower blood sugar levels).
- Take JANUMET with meals to lower your chance of an upset stomach.
- Continue to take JANUMET as long as your doctor prescribes it so you can continue to help control your blood sugar levels.

You may need to stop JANUMET 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, diarrhoea 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.

If you take more JANUMET than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take JANUMET

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.

POSSIBLE SIDE EFFECTS

JANUMET may cause side effects.

Not all side effects reported for JANUMET are included in this leaflet. Should your general health worsen while taking JANUMET, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking JANUMET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Feeling sick (nausea) or being sick (vomiting), abdominal pain, muscular cramps, unexplained weight loss, rapid breathing and feeling cold or uncomfortable. In rare cases, metformin, one of the medicines in JANUMET, can cause a serious side effect

called lactic acidosis (too much lactic acid in your blood). This is more common in people whose kidneys are not working properly. Lactic acidosis is a medical emergency that can cause death and must be treated in the hospital. Stop taking JANUMET if you get any of the above symptoms of lactic acidosis and see your doctor immediately.

- 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 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 and call your doctor right away if you experience these symptoms.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Some patients have experienced kidney problems (sometimes requiring dialysis) or hepatitis (a problem with your liver) while taking JANUMET.

The following are mild side effects of JANUMET that are seen frequently.

Tell your doctor if you notice any of the following:

- low blood sugar
- nausea
- vomiting
- abdominal pain
- diarrhoea

- constipation
- flatulence
- loss of appetite
- foot swelling
- headache
- upper respiratory infection
- stuffy or runny nose and sore throat
- arm or leg pain
- painful joint disease, most frequently affecting the hips, knees and spine
- a metallic taste.

The following are mild side effects of JANUMET that are seen less frequently.

Tell your doctor if you notice any of the following:

- drowsiness
- dizziness
- decreased vitamin B₁₂ levels
- redness of the skin (rash) or itching.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

HOW CAN I LEARN MORE ABOUT JANUMET AND DIABETES?

You may obtain further information from your doctor or pharmacist, who has more detailed information.

STORING AND DISPOSING OF JANUMET

Store at or below 30 °C.

Keep all medicines out of reach and sight of children.

Do not use this medicine after the month and year following EXP.: on the container.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF JANUMET

JANUMET Tablets are packed in opaque PVC/PE/PVDC, aluminium push through blisters in packs of 28 or 56 tablets with blisters containing 14 tablets.

IDENTIFICATION OF JANUMET

JANUMET 50/500 mg: A light pink, capsule-shaped film-coated tablet, debossed '575' on one side and blank on the other.

JANUMET 50/850 mg: A pink, capsule-shaped film-coated tablet, debossed '515' on one side and blank on the other.

JANUMET 50/1 000 mg: A red, capsule-shaped film-coated tablet, debossed '577' on one side blank on the other.

REGISTRATION NUMBERS

JANUMET 50/500 mg: 42/21.2/1089

JANUMET 50/850 mg: 42/21.2/1090

JANUMET 50/1 000 mg: 42/21.2/1091

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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