

JANUMET[®] FILM-COATED TABLETS

Sitagliptin phosphate/metformin hydrochloride (50 mg/500 mg, 50 mg/850 mg, 50mg/1000 mg)

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What JANUMET 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.

Why has my doctor prescribed JANUMET?

Your doctor has prescribed JANUMET, 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 can I learn more about JANUMET and diabetes?

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

How JANUMET works

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

Before you use JANUMET

– When you must not use it

You should not use JANUMET if you:

- have type 1 diabetes.
- have severely reduced kidney function.
- are allergic to sitagliptin (JANUVIA[®]), metformin hydrochloride, or any other components of JANUMET. See “**Product description, Ingredients**” for a complete list of all ingredients in JANUMET.
- 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 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 unstable congestive heart failure
- drink alcohol a lot (all the time or short-term “binge” drinking)
- are pregnant or planning to become pregnant
- are breast-feeding
- have or have had an allergic reaction to sitagliptin (JANUVIA), metformin, or JANUMET
- are taking any prescription medicines
- are taking non-prescription medicines
- are taking any herbal supplements
- 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 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

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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 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 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, 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 are not effective in children and adolescents 10 to 17

years of age with type 2 diabetes. JANUMET have not been studied in children younger than 10 years of age.

– Taking other medicines

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

How to use JANUMET

– How much to use

- Use JANUMET twice daily.
- Use 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.
- Your doctor may prescribe JANUMET along with a sulfonylurea, a glitazone or insulin (other medicines to lower blood sugar).

– When to use it

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

– How long to use it

Continue to take JANUMET 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.

– If you use too much (overdose)

If you take too much JANUMET, call your doctor or poison control center right away.

While you are using JANUMET

– Things you must do

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, 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. 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.

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

– Things you must not do

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

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

– Things to be careful of

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

Can I drive or operate machinery while using JANUMET?

No studies of the effects of JANUMET on the ability to drive and use machines have been performed. However, JANUMET is not expected to affect the ability to drive and use machines.

Side effects

In rare cases, metformin, one of the medicines in JANUMET, 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 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 heartbeat.
- 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 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 side effects most often happen at the beginning of the treatment with JANUMET. It helps if you spread the doses over the day and if you take JANUMET with or straight after a meal. If symptoms continue, stop taking JANUMET and talk to your doctor.

Common side effects in patients taking metformin 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 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 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) were generally similar to metformin taken alone. Taking JANUMET 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 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 is used with a sulfonylurea medicine, constipation may occur.

When JANUMET was used in combination with rosiglitazone (a

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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 or sitagliptin, one of the medicines in JANUMET. These side effects have been reported when JANUMET 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 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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal

– Storage

- Store below 30°C (86°F).
- Keep JANUMET and all medicines safely away from children.

How long should I keep my medicine?

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 50/500 mg Tablet: Light pink, film-coated tablet, debossed '575' on one side and blank on the other.

JANUMET 50/850 mg Tablet: Pink, film-coated tablet, debossed '515' on one side and blank on the other.

JANUMET 50/1000 mg Tablet: Red, film-coated tablet, debossed '577' on one side and blank on the other.

– Ingredients

-Active ingredient:
JANUMET (*sitagliptin phosphate/metformin HCl*, MSD) is a tablet that contains sitagliptin and metformin hydrochloride as active ingredients:

- JANUMET 50 mg sitagliptin phosphate/500 mg metformin hydrochloride
- JANUMET 50 mg sitagliptin phosphate/850 mg metformin hydrochloride
- JANUMET 50 mg sitagliptin phosphate/1000 mg metformin hydrochloride

-Inactive ingredient:

JANUMET contains the following inactive ingredients: microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, sodium stearyl fumarate and purified water. The film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black iron oxide.

– MAL number

- JANUMET 50/500 mg: MAL20081789ARZ
- JANUMET 50/850 mg: MAL20081790ARZ
- JANUMET 50/1000 mg: MAL20081791ARZ

Manufacturer

MSD International GmbH
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70 Tuas West Drive,
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Singapore, SG-638414, Singapore

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level 22
The Ascent, Paradigm No. 1
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47301 Petaling Jaya
Selangor, Malaysia

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