Package leaflet: Information for the patient

Janumet® 50 mg/1,000 mg film-coated tablets
sitagliptin/metformin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Janumet is and what it is used for

Janumet contains two different medicines called sitagliptin and metformin.
- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

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 (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take Janumet

Do not take Janumet:
- if you are allergic to sitagliptin or metformin or any of the other ingredients of this medicine (listed in section 6)
- if you have diabetic ketoacidosis (a complication of diabetes with rapid weight loss, nausea or vomiting) or have had a diabetic coma
- if you have problems with your kidneys
- if you have a severe infection or are dehydrated
- if you are going to have an X-ray where you will be injected with a dye. You will need to stop taking Janumet at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working

- if you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties
- if you have liver problems
- if you drink alcohol to excess (either every day or only from time to time)
- if you are breast-feeding

Do not take Janumet if any of the above apply to you and talk with your doctor about other ways of managing your diabetes. If you are not sure, talk to your doctor, pharmacist, or nurse before taking Janumet.

Warnings and precautions
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Janumet (see section 4).

Talk to your doctor or pharmacist before taking Janumet:
- if you have or have had a disease of the pancreas (such as pancreatitis)
- if you have or have 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 (see section 4)
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- if you have diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- if you experience some of the following symptoms: feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing. Metformin hydrochloride, one of the ingredients in Janumet, can cause a rare but serious side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital. If you experience some of the symptoms of lactic acidosis stop taking Janumet and consult a doctor immediately (see section 4)
- if you have or have had an allergic reaction to sitagliptin, metformin, or Janumet (see section 4)
- if you are taking a sulphonylurea or insulin, diabetes medicines, together with Janumet, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin
- if you are going to have an operation under general, spinal or epidural anaesthetic. You may need to stop taking Janumet for a couple of days before and after the procedure

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Janumet.

During treatment with Janumet, your doctor will check your kidney function at least once a year and more frequently if you are elderly or if your kidney function is borderline or at risk of worsening

Children and adolescents
Children and adolescents below 18 years should not use this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and Janumet
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines are particularly important:
- medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- specific medicines for the treatment of high blood pressure (ACE inhibitors)
- medicines which increase urine production (diuretics)
- specific medicines for the treatment of bronchial asthma (β-sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines

- certain medicines used to treat stomach problems such as cimetidine
- digoxin (to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with Janumet.

Janumet with alcohol
Avoid alcohol while taking Janumet since alcohol may increase the risk of lactic acidosis (please see section 4).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take this medicine during pregnancy or if you are breast-feeding. See section 2, **Do not take Janumet**.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

3. How to take Janumet

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take one tablet:
  - twice daily by mouth
  - with meals to lower your chance of an upset stomach.

- Your doctor may need to increase your dose to control your blood sugar.

You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

Sometimes you may need to stop taking your medicine for a short time. Talk to 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 due to get an injection of dye or contrast agent as part of an X-ray

If you take more Janumet than you should
If you take more than the prescribed dosage of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing.

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 this medicine.

If you stop taking Janumet
Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first. If you stop taking Janumet, your blood sugar may rise again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking Janumet and contact a doctor immediately if you notice any of the following serious side effects:
- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).

Very rarely (may affect up to 1 in 10,000 people) patients taking metformin (one of the active substances of Janumet) have experienced a serious condition called lactic acidosis (too much lactic acid in your blood). This is more common in people whose kidneys are not working properly. Stop taking this medicine and see a doctor straight away if you notice any of the following symptoms:
- feeling sick (nausea) or being sick (vomiting), stomach ache (abdominal pain), muscular cramps, unexplained weight loss, rapid breathing, and feeling cold or uncomfortable.

If you have a serious allergic reaction (frequency not known), including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients taking metformin have experienced the following side effects after starting sitagliptin:
Common (may affect up to 1 in 10 people): low blood sugar, nausea, flatulence, vomiting
Uncommon (may affect up to 1 in 100 people): stomach ache, diarrhoea, constipation, drowsiness

Some patients have experienced diarrhoea, nausea, flatulence, constipation, stomach ache or vomiting when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking this medicine with a sulphonylurea such as glimepiride:
Very common (may affect more than 1 in 10 people): low blood sugar
Common: constipation

Some patients have experienced the following side effects while taking this medicine in combination with pioglitazone:
Common: swelling of the hands or legs

Some patients have experienced the following side effects while taking this medicine in combination with insulin:
Very common: low blood sugar
Uncommon: dry mouth, headache

Some patients have experienced the following side effects during clinical studies while taking sitagliptin alone (one of the medicines in Janumet) or during post-approval use of Janumet or sitagliptin alone or with other diabetes medicines:
Common: low blood sugar, headache, upper respiratory infection, stuffy or runny nose and sore throat, osteoarthritis, arm or leg pain.
Uncommon: dizziness, constipation
Frequency not known: kidney problems (sometimes requiring dialysis); vomiting; joint pain; muscle pain; back pain; interstitial lung disease.

Some patients have experienced the following side effects while taking metformin alone:
Very common: nausea, vomiting, diarrhoea, stomach ache and loss of appetite. These symptoms may happen when you start taking metformin and usually go away
Common: a metallic taste
Very rare: decreased vitamin B12 levels, hepatitis (a problem with your liver), hives, redness of the skin (rash) or itching

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).
By reporting side effects you can help provide more information on the safety of this medicine.
United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website:www.hpra.ie; e-mail: medsafety@hpra.ie
Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. How to store Janumet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of the month.

Do not store above 30°C.

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.

6. Contents of the pack and other information

What Janumet contains

- The active substances are sitagliptin and metformin. Each film-coated tablet (tablet) contains sitagliptin phosphate monohydrate equivalent to 50 mg of sitagliptin and 1,000 mg of metformin hydrochloride.

- The other ingredients are: In the tablet core: microcrystalline cellulose (E460), povidone K 29/32 (E1201), sodium lauril sulfate, and sodium stearyl fumarate. In addition, the film coating contains: poly(vinyl alcohol), macrogol 3350, talc (E553b), titanium dioxide (E171), iron oxide red (E172), and iron oxide black (E172).

What Janumet looks like and contents of the pack

Capsule-shaped, red film-coated tablet with “577” debossed on one side.

Opaque blisters (PVC/PE/PVDC and aluminum). Packs of 14, 28, 56, 60, 112, 168, 180, 196 film-coated tablets, multi-packs containing 196 (2 packs of 98) and 168 (2 packs of 84) film-coated tablets. Pack of 50 x 1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

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Manufacturer
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Detailed information on this medicine is available on the website of the European Medicines Agency web site: http://www.ema.europa.eu.

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