

## **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.

#### **What is in this leaflet:**

1. What Janumet is and what it is used for
2. What you need to know before you take Janumet
3. How to take Janumet
4. Possible side effects
5. How to store Janumet
6. Contents of the pack and other information

#### **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 improve the levels of insulin 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 also called non-insulin-dependent diabetes mellitus, or NIDDM. 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. If you are not sure, talk to your doctor or 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 had pancreatitis, gallstones, alcoholism or very high triglycerides. These medical conditions can increase your chance of getting pancreatitis, or getting it again (see section 4).
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- if you experience some of the following symptoms: feeling cold or uncomfortable, severe nausea or vomiting, abdominal pain, 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 ( $\beta$ -sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines

- certain medicines used to treat stomach problems such as cimetidine
- digoxin (to treat irregular heart beat)

### **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.

Metformin passes into human milk in small amounts. It is not known whether sitagliptin passes into human milk. It is not known if this medicine passes into human breast milk. You must not take this medicine if you are breast-feeding or plan to breast-feed.

### **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.

- This medicine should be taken:
  - 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 your diet during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day. If you are overweight continue your energy-restricted diet as instructed.

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, stomachache, 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.

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Janumet (frequency not known, cannot be estimated from the available data). 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.

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), stomachache (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): stomachache, diarrhoea, constipation, drowsiness.

Some patients have experienced diarrhoea, nausea, flatulence, constipation, stomachache or vomiting when starting the combination of sitagliptin and metformin together.

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: low blood sugar, 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, stomachache 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,

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **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 50 mg of sitagliptin (as phosphate monohydrate) and 1,000 mg of metformin hydrochloride.
- The other ingredients are: microcrystalline cellulose (E460), povidone K 29/32 (E1201), sodium lauril sulfate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: 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, 112, 168, 196 film-coated tablets, multi-packs containing 196 (2 packs of 98) 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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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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