

# JANUMET™

*sitagliptin phosphate/metformin HCl*

50 mg/500 mg, 50 mg/850 mg, 50 mg/1000 mg tablets

## What is in this leaflet

This leaflet answers some common questions about JANUMET. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking JANUMET against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

## What JANUMET is used for

JANUMET (*sitagliptin phosphate/metformin HCl*) is a tablet that contains sitagliptin phosphate 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

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.

- 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 (hypoglycaemia).

Your doctor has prescribed JANUMET to help lower your blood sugar, which is too high because of your type 2 diabetes, along with a recommended diet and exercise programme.

## 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.

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.

## **Before you take JANUMET**

### **When you must not take it**

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 (JANUVIA), metformin hydrochloride, or any other components of JANUMET. (See What JANUMET is used for, for a complete list of all ingredients in JANUMET.)
- have conditions called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine)
- 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 take it**

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)
- 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

### **Taking other medicines**

JANUMET may affect how well other medicines work and some medicines can affect how well JANUMET works. Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

### **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.

### **Use in pregnancy and breast-feeding**

Women who are pregnant or plan to become pregnant should consult with their doctor before taking JANUMET. JANUMET is not recommended for use during pregnancy.

It is not known if JANUMET passes into human breast milk. You should not use JANUMET if you are breast-feeding or plan to breast-feed.

### **Effects on the Ability to Drive and Use Machinery**

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

## **How to take JANUMET**

### **How much to take**

- 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.
- Your doctor may prescribe JANUMET along with a sulfonylurea (another medicine to lower blood sugar).
- 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.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

You may need to stop taking 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 forget to take 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 take too much (overdose)**

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much JANUMET. Do this even if there are no signs of discomfort or poisoning.

## **While you are using JANUMET**

### **Things you must do**

If you become pregnant while taking JANUMET, tell your doctor immediately.

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

## **Things you must not do**

Do not give JANUMET to anyone else, even if they have the same condition as you.

## **Things that may help**

Along with taking JANUMET, follow your doctor's recommendations for:

- healthy eating/diet
- active lifestyle/exercise
- weight loss

These can help your body use your blood sugar better.

## **Adverse Effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking JANUMET. In rare cases, metformin, one of the medicines in JANUMET, can cause a serious adverse 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 taking 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 diarrhoea
- you feel cold, especially in your arms and legs
- you feel dizzy or lightheaded
- you have a slow or irregular heart beat
- your medical condition suddenly changes.

### **You have a higher chance of getting lactic acidosis if you:**

- have kidney 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 diarrhoea. 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
- are 80 years of age or older and have not had your kidney function tested.

Common adverse effects in patients taking metformin alone include metallic taste in the mouth, epigastric discomfort, nausea and vomiting: rarely, diarrhoea and anorexia.

Common adverse effects in patients taking sitagliptin alone include stuffy or running nose and sore throat, upper respiratory tract infection and headache.

Adverse 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 adverse 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, low blood sugar (hypoglycaemia), due to the sulfonylurea, can occur. Lower doses of the sulfonylurea medicine may be

required. In addition, when JANUMET is used with a sulfonylurea medicine, constipation may occur.

Additional adverse effects have been reported in general use with JANUMET or sitagliptin, one of the medicines in JANUMET. These adverse 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.

All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Other adverse effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice any possible adverse effects, or if any known adverse effect does not go away or gets worse.

Ask your doctor or pharmacist to answer any questions you may have.

## **After using JANUMET**

### **Storage**

Keep JANUMET in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

If your doctor tells you to stop taking JANUMET or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

## **Product description**

### **What it looks like**

JANUMET comes as three strengths of tablets:

- 50 mg/500 mg tablet - a light pink capsule-shaped film-coated tablet with "575" debossed on one side and plain on the other.
- 50 mg/850 mg tablet - a pink capsule-shaped film-coated tablet with "515" debossed on one side and plain on the other.
- 50 mg/1000 mg tablet - a red capsule-shaped film-coated tablet with "577" debossed on one side and plain on the other.

## **Ingredients**

### Active ingredients:

- sitagliptin phosphate
- metformin hydrochloride

### Inactive ingredients:

- microcrystalline cellulose
- polyvinylpyrrolidone
- sodium lauryl sulfate
- sodium stearyl fumarate

The film coating contains the following inactive ingredients:

- polyvinyl alcohol
- polyethylene glycol (macrogol)
- talc
- titanium dioxide
- red iron oxide
- black iron oxide

JANUMET does not contain lactose, gluten, tartrazine or any other azo dyes.

## **Supplier**

JANUMET is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited  
P O Box 99851  
Newmarket  
Auckland  
NEW ZEALAND  
Tel: 0800 500 673

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