Product Name: JANUMET 50/500, 50/850 and 50/1 000 mg	Component: English Patient Information Leaflet Clinical Approval: 17 July 2020 Date Approved: 14 September 2012

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

JANUMET® 50/500 mg Tablets

JANUMET® 50/850 mg Tablets

JANUMET® 50/1 000 mg Tablets

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 your 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.

WHAT JANUMET CONTAINS

The active substance is: JANUMET is a tablet that contains 50 mg sitagliptin as a phosphate and 500 or 850 or 1 000 mg metformin hydrochloride as active ingredients.

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

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

JANUMET is sugar free.

WHAT JANUMET IS USED FOR

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

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

BEFORE YOU TAKE JANUMET

Do not take JANUMET if you:

- are allergic to sitagliptin, metformin hydrochloride or any other components of JANUMET.
- have type 1 diabetes.
- have moderate to severe kidney problems.
- have a heart problem called congestive heart failure that is treated with medicines.

- 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 breastfeeding, or if you are planning to become pregnant.
- have conditions called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).

Take special care with JANUMET

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

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. If you are taking JANUMET, you should not breastfeed your baby.

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 and JANUMET

Always tell your healthcare professional if you are taking any other medicine.

If you are taking other medicines on a regular basis (prescription or non-prescription), including complementary and traditional medicines concomitant use of JANUMET

with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

JANUMET may affect the actions of other medicines and some medicines can affect the action of JANUMET.

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 for you, tell 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 change your dose to control your 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.

Your doctor may ask you to stop taking JANUMET for a short time 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.

Contact your doctor if any of the above applies to you.

Use in children

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

Use in 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.

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 can have 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 happens, 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 medicine to treat your allergic reaction and a different medicine 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.

Frequent side effects

- low blood sugar; signs and symptoms of low blood sugar may include headache, drowsiness, irritability, hunger, dizziness, confusion, sweating, feeling jittery, weakness and fast heartbeat
- nausea
- vomiting
- abdominal pain
- diarrhoea
- constipation
- flatulence

- loss of appetite
- swelling of feet
- 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.

Less frequent side effects

- drowsiness
- dizziness
- decreased vitamin B12 levels sometimes associated with anaemia
- redness of the skin (rash) or itching
- joint pain
- muscle aches
- arm and leg pain
- back pain.

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

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 shown 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 packaged in opaque PVC/PE/PVDC aluminium push through blisters in packs of 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

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