Product Name: JANUVIA 25, 50 and 100 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

JANUVIA® 25 Tablets

JANUVIA® 50 Tablets

JANUVIA® 100 Tablets

Read all of this leaflet carefully before you start taking JANUVIA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- JANUVIA 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 JANUVIA CONTAINS

The active substance is: JANUVIA (sitagliptin phosphate) is a tablet that contains 25, 50 or 100 mg of sitagliptin as the active ingredient.

The other ingredients are anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose and sodium stearyl fumarate.

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

JANUVIA Tablets are sugar free.

WHAT JANUVIA IS USED FOR

JANUVIA belongs to a class of medicines that lowers 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 JANUVIA to help lower your blood sugar, which is too high because you have type 2 diabetes.

BEFORE YOU TAKE JANUVIA

Do not take JANUVIA:

If you are allergic to sitagliptin or any of the other ingredients in JANUVIA. A list of ingredients can be found at the beginning of this leaflet under **WHAT JANUVIA CONTAINS**.

If you have type 1 diabetes.

Take special care with JANUVIA

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

Tell your doctor if you have or have had:

- any allergies.

While taking JANUVIA

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving JANUVIA. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking JANUVIA and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Taking JANUVIA with food and drink

JANUVIA can be taken with or without food.

Pregnancy and Breastfeeding

JANUVIA is not recommended for use during pregnancy.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking JANUVIA.

It is not known if JANUVIA passes into breast milk. If you are taking JANUVIA you should not breastfeed your baby.

Driving and using machinery

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

Taking other medicines with JANUVIA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you are taking other medicines on a regular basis (prescription or non-prescription), including complementary or traditional medicines, the use of JANUVIA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE JANUVIA

Do not share JANUVIA prescribed for you with others.

Always take JANUVIA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is to take:

One 100 mg tablet once a day by mouth, with or without food.

If you have the impression that the effect of JANUVIA is too strong or too weak for you, tell your doctor or pharmacist.

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe JANUVIA along with certain other medicines that lower blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking JANUVIA.

Use in Children

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

Use in the Elderly

No dosage adjustment is necessary based on age.

If you take more JANUVIA 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 JANUVIA

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 JANUVIA.

POSSIBLE SIDE EFFECTS

JANUVIA can have side effects.

Not all side effects reported for JANUVIA are included in this leaflet. Should your general health worsen while taking JANUVIA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking JANUVIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 JANUVIA 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 JANUVIA 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) while taking JANUVIA.

Tell your doctor if you notice any of the following:

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
- flatulence
- foot swelling
- 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
- flu-like symptoms
- swelling of the arms and legs.

Less frequent side effects

- abdominal pain
- diarrhoea
- constipation

- vomiting
- drowsiness
- dizziness
- runny nose
- dry mouth
- upper respiratory infection
- stuffy or runny nose and sore throat
- constipation
- headache
- joint pain
- muscle aches
- arm or leg pain
- back pain.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF JANUVIA

Store at or below 30 °C.

Do not use JANUVIA after the month and year shown following EXP.: on the container.

Keep all medicines out of reach and sight of children.

The blister should be kept in the carton until required for use.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF JANUVIA

JANUVIA 25, 50 and 100 is packed in opaque PVDC/PE/PVC push-through blisters (referred to as PVDC blister) with push-through aluminium lidding. Packs of 28 tablets with blisters of 14 tablets. The blisters are opened by pushing the tablets through the foil.

IDENTIFICATION OF JANUVIA

JANUVIA 25: A pink, round, biconvex, film-coated tablet with 221 on one side and plain on the other.

JANUVIA 50: A light beige, round, biconvex, film-coated tablet with 112 on one side and plain on the other.

JANUVIA 100: A beige, round, biconvex, film-coated tablet with 277 on one side and plain on the other.

REGISTRATION NUMBERS

JANUVIA 25: 41/21.2/0354

JANUVIA 50: 41/21.2/0355

JANUVIA 100: 41/21.2/0356

NAME AND ADDRESS OF REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

Tel. No.: 011 655 3000

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