

PATIENT INFORMATION LEAFLET

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 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.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

JANUVIA® 25 mg Tablets

JANUVIA® 50 mg Tablets

JANUVIA® 100 mg Tablets

WHAT JANUVIA CONTAINS

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

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

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

JANUVIA Tablets are sugar free.

WHAT JANUVIA IS USED FOR

JANUVIA belongs to a class of medicines you take by mouth, called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) 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.

- JANUVIA helps to improve the levels of insulin after a meal.

Why has my doctor prescribed JANUVIA?

Your doctor has prescribed JANUVIA to help lower your blood sugar levels, which is too high because you have type 2 diabetes. JANUVIA can be used alone or in combination with certain other medicines that lower blood sugar levels, along with a recommended diet and exercise program.

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.

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.

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, planning to become pregnant or breastfeeding your baby while taking JANUVIA, please contact your doctor, pharmacist or other healthcare professional for advice.

It is not known if JANUVIA passes into breast milk. You should not use JANUVIA if you are breastfeeding or plan to breastfeed.

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

JANUVIA may be taken with most 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 to take is:

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, talk to 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 levels.

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.

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 may cause 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 happen, 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 medication to treat your allergic reaction and a different medication 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.

The following are mild side effects of JANUVIA that are seen frequently.

Tell your doctor if you notice any of the following:

- low blood sugar
- 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.

The following are mild side effects of JANUVIA that are seen less frequently.

Tell your doctor if you notice any of the following:

- abdominal pain
- diarrhoea
- constipation
- vomiting
- drowsiness
- dizziness.

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. Protect from moisture.

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

IDENTIFICATION OF JANUVIA

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

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

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

REGISTRATION NUMBERS

JANUVIA 25 mg: 41/21.2/0354

JANUVIA 50 mg: 41/21.2/0355

JANUVIA 100 mg: 41/21.2/0356

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

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DATE OF PUBLICATION

14 September 2012

WPPI-JAN-T-122005 (partial 04-2010)