

JANUVIA[®]

sitagliptin phosphate

25 mg, 50 mg & 100 mg tablets

What is in this leaflet

This leaflet answers some common questions about JANUVIA. 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 JANUVIA 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 JANUVIA is used for

JANUVIA is a member of 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.
- JANUVIA decreases the amount of sugar made by the body.
- JANUVIA works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. JANUVIA also lowers blood sugar between meals.
- JANUVIA by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not work when your blood sugar is low.

Your doctor has prescribed JANUVIA to help lower your blood sugar, which is too high because of your type 2 diabetes. JANUVIA can be used alone or in combination with certain other medicines that lower blood sugar, 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 disease, kidney disease, blindness, and amputation.

High blood sugar can be lowered by diet and exercise, and by certain medicines.

Before you take JANUVIA

When you must not take it

Do not take JANUVIA if:

- you are allergic to any of the ingredients in JANUVIA.

Before you start to take it

Tell your doctor if you have or have had:

- type 1 diabetes
- diabetic ketoacidosis (increased ketones in the blood or urine)
- any kidney problems, or any past or present medical problems
- an allergic reaction to JANUVIA.

Taking other medicines

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.

JANUVIA can be taken with most other medicines.

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

In studies, JANUVIA worked well in and was well-tolerated by older adult patients. No dosage adjustment is necessary based on age.

Use in pregnancy and breast-feeding

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

It is not known if JANUVIA passes into breast milk. You should not use JANUVIA 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 JANUVIA affects your ability to drive a car or operate machinery.

How to take JANUVIA

How much to take

Take JANUVIA exactly as your doctor has prescribed. The recommended dose is to take:

- one 100 mg tablet
- once a day
- by mouth, with or without food

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.

Continue to take JANUVIA as long as your doctor prescribes it so you can continue to help control your 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 programme while taking JANUVIA.

Take JANUVIA only when prescribed by your doctor.

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.

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 JANUVIA.

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 JANUVIA. Do this even if there are no signs of discomfort or poisoning.

While you are using JANUVIA

Things you must do

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

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

Things you must not do

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

Things that may help

Along with taking JANUVIA, 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 JANUVIA.

Like all prescription medicines, JANUVIA may cause adverse effects. Sometimes they are serious, most of the time they are not. In studies, adverse effects usually were mild and did not cause patients to stop taking JANUVIA. The adverse effects reported in patients treated with JANUVIA were similar to adverse effects in patients treated with a tablet containing no medication (placebo).

When JANUVIA is used in combination with a sulfonylurea medicine, low blood sugar with

symptoms (hypoglycaemia) due to the sulfonylurea, can occur. Lower doses of the sulfonylurea medicine may be required.

When JANUVIA and metformin were started together, the following adverse effects were reported:

- diarrhoea
- indigestion
- flatulence
- vomiting
- headache

When JANUVIA and pioglitazone were started together, the adverse effect of decreased blood sugar measurements without symptoms of hypoglycaemia was reported.

When JANUVIA was used in combination with metformin and rosiglitazone, the following adverse effects were reported:

- headache
- low blood sugar with symptoms (hypoglycaemia)
- diarrhoea
- upper respiratory infection
- nausea
- cough
- fungal skin infection
- swelling of the hands or legs
- vomiting

Additional adverse effects have been reported in general use with JANUVIA, by itself 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 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.
- inflammation of the pancreas
- kidney problems (sometimes requiring dialysis)
- upper respiratory infection
- stuffy or runny nose and sore throat
- constipation
- vomiting
- headache.

Tell your doctor if you notice any possible adverse effects.

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

After using JANUVIA

Storage

Keep JANUVIA 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 JANUVIA 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

JANUVIA comes as three strengths of tablets:

- 25 mg tablet - a pink round film-coated tablet with 221 on one side and plain on the other.
- 50 mg tablet - a light beige round film-coated tablet with 112 on one side and plain on the other.
- 100 mg tablet - beige round film-coated tablet with 277 on one side and plain on the other.

Ingredients

Active ingredient:

- sitagliptin phosphate

Inactive ingredients:

- microcrystalline cellulose
- anhydrous dibasic calcium phosphate
- croscarmellose sodium
- magnesium stearate
- sodium stearyl fumarate

The film coating contains the following inactive ingredients:

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

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

Supplier

JANUVIA 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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