

JANUVIA®

Sitagliptin phosphate monohydrate

Consumer Medicine Information

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 used to lower blood sugar levels in patients with type 2 diabetes mellitus alone or in combination with certain other medicines (metformin, medicines such as rosiglitazone and pioglitazone, a sulfonylurea medicine such as glimepiride, gliclazide and glibenclamide, or insulin), when diet plus

exercise or the other medicine(s) do not provide adequate blood sugar level control.

Type 2 diabetes mellitus

Type 2 diabetes mellitus 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.

How JANUVIA works

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 mellitus 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.

Before you take JANUVIA

When you must not take it

Do not take JANUVIA if:

- **you have an allergy to JANUVIA or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.

- **the packaging is torn or shows signs of tampering.**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking JANUVIA, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you are pregnant or intend to become pregnant.**

JANUVIA is not recommended for use during pregnancy.

- 2. you are breastfeeding or plan to breastfeed.**

JANUVIA should not be used while breastfeeding or if planning to breastfeed.

- 3. you have or have had type 1 diabetes mellitus or a condition called diabetic ketoacidosis (increased ketones in the blood or urine).**

JANUVIA should not be used for the treatment of these conditions.

- 4. you have any kidney problems or any past or present medical problems.**

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

- 5. you have an allergic reaction to JANUVIA or you have any allergies to any other medicines or other substances such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell him/her before you take any JANUVIA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines and herbal supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

JANUVIA can be taken with most other medicines.

How to take JANUVIA

How much to take

Take JANUVIA only when prescribed by your doctor.

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, and monitor your kidney function.

Your doctor may prescribe JANUVIA on its own, or with certain other medicines that lower blood sugar.

Follow all directions given to you by your doctor and pharmacist carefully.

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

When to take it

Take your JANUVIA at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

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's recommended diet, exercise and weight loss program while taking JANUVIA.

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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose of JANUVIA to make up for the dose that you missed.

If you have trouble remembering to take your tablet, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), 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.

Side 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 side effects. In studies, side effects usually were mild and did not cause patients to stop taking JANUVIA.

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

Tell your doctor if you notice or have any of the following and they worry you:

- signs of an infection of the breathing passages, including runny nose, sore throat, cough
- soreness in the back of the nose and throat and discomfort when swallowing
- headache
- flu-like symptoms

JANUVIA may occasionally cause stomach discomfort and diarrhoea.

Tell your doctor immediately if you notice any of the following:

- Low blood sugar (hypoglycaemia) when JANUVIA is used in combination with a sulfonylurea medicine or with insulin. Due to the sulfonylurea or insulin, causing hypoglycaemia, the dose of your sulfonylurea medicine or insulin may need to be reduced while you use JANUVIA.
- Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in

patients receiving JANUVIA. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking JANUVIA.

Tell your doctor immediately or go to the accident and emergency at your nearest hospital if you notice any of the following:

- 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.

Additional side effects have been reported in general use with JANUVIA, by itself and/or with other diabetes medicines:

- Kidney problems (sometimes requiring dialysis)
- Constipation
- Diarrhoea
- Vomiting

- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using JANUVIA

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

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 - A beige, round, film coated tablet with "277" on one side and plain on the other.

A box of JANUVIA contains 28 tablets. JANUVIA 100 mg tablets may also be supplied in packs of 7 tablets to start treatment.

Ingredients

Active ingredient:

Sitagliptin 25, 50 or 100 mg per tablet (as free base)

Inactive ingredients:

- Microcrystalline cellulose
- Calcium hydrogen phosphate
- Croscarmellose sodium
- Magnesium stearate
- Sodium stearyl fumarate

Ingredients of film-coating:

- polyvinyl alcohol,
- macrogol 3350
- talc purified
- titanium dioxide
- iron oxide red
- iron oxide yellow

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

Supplier

JANUVIA is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A,

26 Talavera Road

MACQUARIE PARK NSW 2113

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Australian Register Numbers:

25 mg tablet - AUST R 133188

50 mg tablet - AUST R 133187

100 mg tablet - AUST R 133182

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This CMI leaflet was current at the time of printing. To check if it has been updated, please view our website, (www.msinfo.com.au/januviaacmi), or ask your pharmacist.