

JANUVIA[®] TABLET

Sitagliptin Phosphate (25mg, 50mg, 100mg)

What is in this leaflet

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What JANUVIA is taken for

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

- 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 (hypoglycemia) because it

does not work when your blood sugar is low.

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 is also called non-insulin-dependent diabetes mellitus, or NIDDM.

Why has my doctor prescribed JANUVIA?

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 program.

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
 - gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis.

- Taking other medicines
JANUVIA may be taken with most medicines. Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

In particular, tell your doctor:

- if you are taking digoxin (a medicine used to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with JANUVIA.

How to take JANUVIA

- How much to take and When to take it
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

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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.

- 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 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. Do not take a double dose of JANUVIA.

- If you take too much (overdose)

If you take more than the prescribed dosage of JANUVIA, contact your doctor immediately.

While you are taking JANUVIA

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking JANUVIA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

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

- Things to be careful of

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.

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.

Use in children

JANUVIA is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. JANUVIA has not been studied in children younger than 10 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.

Can I drive or operate machinery while using JANUVIA?

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

Side effects

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. The side effects reported in patients treated with JANUVIA were similar to side effects in patients treated with a tablet containing no medication (a placebo).

When JANUVIA is used in combination with a sulfonylurea medicine or with insulin, low blood sugar with symptoms (hypoglycemia) due to the sulfonylurea or insulin can occur. Lower doses of the sulfonylurea medicine or insulin may be required.

When JANUVIA was used in combination with insulin, the following additional side effects were reported:

- Flu
- Headache

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

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

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

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

- Headache
- Low blood sugar with symptoms (hypoglycemia)
- Diarrhea
- Upper respiratory infection
- Nausea
- Cough
- Fungal skin infection
- Swelling of the hands or legs
- Vomiting

Additional side 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.
- Joint pain.
- Muscle aches.
- Arm or leg pain.
- Back pain.
- Itching.

- Blisters.
- Reduced number of platelets.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFD)]

How can I learn more about JANUVIA and diabetes?

You may obtain further information from your doctor or pharmacist, who has more detailed information.

Storage and disposal of JANUVIA

- Storage

Store up to 30°C (86°F). Keep JANUVIA and all medicines safely away from children.

- Disposal

How long should I keep my medicine?

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

Product description

- What it looks like

JANUVIA 25mg: Pink, round, biconvex, film-coated tablet with “221” on one side and plain on the other. Available in packs of 28s .

JANUVIA 50mg: Light beige, round, biconvex, film coated

tablet with “112” on one side and plain on the other. Available in packs of 28s.

JANUVIA 100mg: Beige, round, biconvex, film coated tablet with “277” on one side and plain on the other. Available in packs of 14s (sample) and 28s (trade).

- Ingredients

Active ingredient: Sitagliptin phosphate

Inactive ingredient:

Microcrystalline cellulose, anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, sodium stearyl fumarate, and propyl gallate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol (macrogol), talc, titanium dioxide, red iron dioxide, and yellow iron oxide.

- MAL numbers:

JANUVIA 25MG TABLET:
MAL20071662ACRZ

JANUVIA 50MG TABLET :
MAL20071663ACRZ

JANUVIA 100MG TABLET :
MAL20071664ACRZ

Manufacturer:

Organon Pharma (UK) Limited
Shotton Lane, Crumlington,
NE23 3JU, United Kingdom.

Product Registration Holder:

Merck Sharp & Dohme
(Malaysia) Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level
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The Ascent, Paradigm No. 1
Jalan SS 7/26A, Kelana Jaya
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Selangor, Malaysia

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