Package leaflet: Information for the patient

Januvia® 100 mg film-coated tablets
Sitagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Januvia is and what it is used for

Januvia contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

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 like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take Januvia

Do not take Januvia
- if you are allergic to sitagliptin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Januvia (see section 4).

Tell your doctor if you have or have had:
- a disease of the pancreas (such as pancreatitis)
- 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 (see section 4).
- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems.
- an allergic reaction to Januvia (see section 4).

This medicine is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents
Children and adolescents below 18 years should not use this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and Januvia
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 taking with Januvia.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not take this medicine during pregnancy.

It is not known if this medicine passes into breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

3. How to take Januvia

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended dose is:
- one 100 mg film-coated tablet
- once a day
- by mouth

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg).

You can take this medicine with or without food and drink.

Your doctor may prescribe this medicine alone or 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 the diet and exercise recommended by your doctor while taking Januvia.

If you take more Januvia than you should
If you take more than the prescribed dosage of this medicine, contact your doctor immediately.

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 this medicine.

If you stop taking Januvia
Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking Januvia and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).

If you have a serious allergic reaction (frequency not known), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced the following side effects after adding sitagliptin to metformin:
Common (may affect up to 1 in 10 people): low blood sugar, nausea, flatulence, vomiting
Uncommon (may affect up to 1 in 100 people): stomach ache, diarrhoea, constipation, drowsiness

Some patients have experienced different types of stomach discomfort when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking sitagliptin in combination with a sulphonylurea and metformin:
Very common (may affect more than 1 in 10 people): low blood sugar
Common: constipation

Some patients have experienced the following side effects while taking sitagliptin and pioglitazone:
Common: flatulence, swelling of the hands or legs

Some patients have experienced the following side effects while taking sitagliptin in combination with pioglitazone and metformin:
Common: swelling of the hands or legs

Some patients have experienced the following side effects while taking sitagliptin in combination with insulin (with or without metformin):
Common: flu
Uncommon: dry mouth

Some patients have experienced the following side effects while taking sitagliptin alone in clinical studies, or during post-approval use alone and/or with other diabetes medicines:
Common: low blood sugar, headache, upper respiratory infection, stuffy or runny nose and sore throat, osteoarthritis, arm or leg pain
Uncommon: dizziness, constipation, itching
Frequency not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie
Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. How to store Januvia

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Januvia contains

- The active substance is sitagliptin. Each film-coated tablet (tablet) contains sitagliptin phosphate monohydrate, equivalent to 100 mg sitagliptin.

- The other ingredients are: In the tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate, anhydrous (E341), croscarmellose sodium (E468), magnesium stearate (E470b), and sodium stearyl fumarate. The tablet film coating contains: poly(vinyl alcohol), macrogol 3350, talc (E553b), titanium dioxide (E171), red iron oxide (E172), and yellow iron oxide (E172).

What Januvia looks like and contents of the pack

Round, beige film-coated tablet with "277" on one side.

Opaque blisters (PVC/PE/PVDC and aluminum). Packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets and 50 x 1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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