Package leaflet: Information for the patient

Sitagliptin Krka 50 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sitagliptin Krka is and what it is used for
2. What you need to know before you take Sitagliptin Krka
3. How to take Sitagliptin Krka
4. Possible side effects
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1. What Sitagliptin Krka is and what it is used for

Sitagliptin Krka 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 Sitagliptin Krka

Do not take Sitagliptin Krka
- 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 Sitagliptin Krka (see section 4).

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Sitagliptin Krka.

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 Sitagliptin Krka (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 effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and Sitagliptin Krka
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 Sitagliptin Krka.

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.

Sitagliptin Krka contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Sitagliptin Krka

Always take use 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.

Sitagliptin Krka 50 mg and 100 mg tablets can be divided into equal doses.

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 Sitagliptin Krka.

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

If you forget to take Sitagliptin Krka
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 to make up for a forgotten dose.

If you stop taking Sitagliptin Krka
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 Sitagliptin Krka 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 - cannot be estimated from the available data), including rash, hives, blisters on the skin/peeling skin and swelling of the face,

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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
Rare: reduced number of platelets
Frequency not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease, bullous pemphigoid (a type of skin blister)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sitagliptin Krka

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 box and blister after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C.
Store in the original package in order to protect from moisture.

Do not throw away any 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 Sitagliptin Krka contains
- The active substance is sitagliptin.
  Each film-coated tablet contains 50 mg sitagliptin.
- The other ingredients are:
  Tablet core:
  microcrystalline cellulose, calcium hydrogen phosphate, croscarmellose sodium, sodium stearyl fumarate and magnesium stearate.
  Film coating:
  Opadry 85F280010 II HP white (containing poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171), talc), red iron oxide (E172) and yellow iron oxide, (E172).
  See section 2 "Sitagliptin Krka contains sodium".

What Sitagliptin Krka looks like and contents of the pack
Sitagliptin Krka 50 mg film-coated tablets (tablets): light orange, round, biconvex, film-coated tablets with score line on one side of the tablet. Tablet is engraved with mark K on one side of the score line and with mark 50 on the other side of the score line (diameter approx. 9 mm, thickness 2.8 – 3.8 mm). The tablet can be divided into equal doses.

Sitagliptin Krka is available in boxes containing 14, 28, 30, 56, 60, 90 and 98 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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