Package leaflet: Information for the patient

Sitagliptin/Metformin hydrochloride Krka 50 mg/850 mg film-coated tablets
Sitagliptin/Metformin hydrochloride Krka 50 mg/1000 mg film-coated tablets
sitagliptin/metformin hydrochloride

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/Metformin hydrochloride Krka is and what it is used for

Sitagliptin/Metformin hydrochloride Krka contains two different medicines called sitagliptin and metformin.
- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called ‘type 2 diabetes mellitus’. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas or glitazones).

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/Metformin hydrochloride Krka

Do not take Sitagliptin/Metformin hydrochloride Krka
- if you are allergic to sitagliptin or metformin or any of the other ingredients of this medicine (listed in section 6)
- if you have severely reduced kidney function
- if you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’

accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell
- if you have a severe infection or are dehydrated
- if you are going to have an X-ray where you will be injected with a dye. You will need to stop taking Sitagliptin/Metformin hydrochloride Krka at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working
- if you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties
- if you have liver problems
- if you drink alcohol to excess (either every day or only from time to time)
- if you are breast-feeding

Do not take Sitagliptin/Metformin hydrochloride Krka if any of the above apply to you and talk with your doctor about other ways of managing your diabetes. If you are not sure, talk to your doctor, pharmacist or nurse before taking Sitagliptin/Metformin hydrochloride Krka.

Warnings and precautions
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving sitagliptin/metformin combination (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/Metformin hydrochloride Krka.

Risk of lactic acidosis
Sitagliptin/Metformin hydrochloride Krka may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Sitagliptin/Metformin hydrochloride Krka for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Sitagliptin/Metformin hydrochloride Krka and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).

- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g., pain or numbness), migraine and deafness.

Talk to your doctor or pharmacist before taking Sitagliptin/Metformin hydrochloride Krka:
- if you have or have had a disease of the pancreas (such as pancreatitis)
- if you have or have had 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)
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- if you have or have had an allergic reaction to sitagliptin, metformin or Sitagliptin/Metformin hydrochloride Krka (see section 4)
- if you are taking a sulphonylurea or insulin, diabetes medicines, together with Sitagliptin/Metformin hydrochloride Krka, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin.

If you need to have major surgery you must stop taking Sitagliptin/Metformin hydrochloride Krka during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Sitagliptin/Metformin hydrochloride Krka.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sitagliptin/Metformin hydrochloride Krka.

During treatment with Sitagliptin/Metformin hydrochloride Krka, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

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/Metformin hydrochloride Krka
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking Sitagliptin/Metformin hydrochloride Krka before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Sitagliptin/Metformin hydrochloride Krka.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dose of Sitagliptin/Metformin hydrochloride Krka. It is especially important to mention the following:

- medicines (taken by mouth, inhalation or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- specific medicines for the treatment of bronchial asthma (β-sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines
- certain medicines used to treat stomach problems such as cimetidine
- ranolazine, a medicine used to treat angina
- dolutegravir, a medicine used to treat HIV infection
- vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)

- digoxin (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/Metformin hydrochloride Krka.

Sitagliptin/Metformin hydrochloride Krka with alcohol
Avoid excessive alcohol intake while taking Sitagliptin/Metformin hydrochloride Krka since this may increase the risk of lactic acidosis (see section "Warnings and precautions").

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. Do not take this medicine if you are breast-feeding. See section 2, **Do not take Sitagliptin/Metformin hydrochloride Krka**.

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 with sitagliptin, 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/Metformin hydrochloride 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/Metformin hydrochloride Krka

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

- Take one tablet:
  - twice daily by mouth
  - with meals to lower your chance of an upset stomach.

- Your doctor may need to increase your dose to control your blood sugar.

- If you have reduced kidney function, your doctor may prescribe a lower dose.

You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

If you take more Sitagliptin/Metformin hydrochloride Krka than you should
If you take more than the prescribed dose of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps or rapid breathing (see section "Warnings and precautions").

If you forget to take Sitagliptin/Metformin hydrochloride 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 of this medicine.

If you stop taking Sitagliptin/Metformin hydrochloride 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 stop taking Sitagliptin/Metformin hydrochloride Krka, your blood sugar may rise again.

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/Metformin hydrochloride 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).

Sitagliptin/Metformin hydrochloride Krka may cause a very rare (may affect up to 1 in 10 000 people), but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens, you must **stop taking Sitagliptin/Metformin hydrochloride Krka and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

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 taking metformin have experienced the following side effects after starting sitagliptin:
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 diarrhoea, nausea, flatulence, constipation, stomach ache or vomiting when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking this medicine with a sulphonylurea such as glimepiride:
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 this medicine in combination with pioglitazone:
Common: swelling of the hands or legs

Some patients have experienced the following side effects while taking this medicine in combination with insulin:
Very common: low blood sugar
Uncommon: dry mouth, headache

Some patients have experienced the following side effects during clinical studies while taking sitagliptin alone (one of the medicines in Sitagliptin/Metformin hydrochloride Krka) or during post-

approval use of sitagliptin/metformin combination or sitagliptin alone 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)

Some patients have experienced the following side effects while taking metformin alone:
Very common: nausea, vomiting, diarrhoea, stomach ache and loss of appetite. These symptoms may happen when you start taking metformin and usually go away;
Common: a metallic taste, decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare: hepatitis (a problem with your liver), hives, redness of the skin (rash) or itching

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sitagliptin/Metformin hydrochloride 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 packaging after EXP. The expiry date refers to the last day of that month.

OPA/Alu/PVC//Alu blisters:
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.
PVC/PE/PVDC/PE/PVC//Alu blisters:
Do not store above 30°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/Metformin hydrochloride Krka contains
- The active substances are sitagliptin and metformin hydrochloride.
  Sitagliptin/Metformin hydrochloride Krka 50 mg/850 mg film-coated tablets:
  Each film-coated tablet contains 50 mg sitagliptin and 850 mg of metformin hydrochloride.
  Sitagliptin/Metformin hydrochloride Krka 50 mg/1000 mg film-coated tablets:
  Each film-coated tablet contains 50 mg sitagliptin and 1000 mg of metformin hydrochloride.
- The other ingredients (excipient(s)) are povidone, microcrystalline cellulose, mannitol, sodium laurilsulfate, magnesium stearate in the tablet core and hypromellose, titanium dioxide (E171), talc, propylene glycol and red ferric oxide (E172) in the film coating. See section 2 "Sitagliptin/Metformin hydrochloride Krka contains sodium".

What Sitagliptin/Metformin hydrochloride Krka looks like and contents of the pack

Sitagliptin/Metformin hydrochloride Krka 50 mg/850 mg film-coated tablets: pink, oval, biconvex, film coated tablets marked with C4 on one side of the tablet (dimensions approx.: 20 x 11 mm).

Sitagliptin/Metformin hydrochloride Krka 50 mg/1000 mg film-coated tablets: dark pink, oval, biconvex, film coated tablets marked with C3 on one side of the tablet (dimensions approx.: 21 x 11 mm).

Sitagliptin/Metformin hydrochloride Krka is available in packs containing:
- 10, 14, 28, 30, 56, 60, 196 and 200 film-coated tablets in blisters,
- 14, 28, 56 and 196 film-coated tablets in blisters, calendar packs.

Not all pack sizes may be marketed.

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

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the member state	**Name of the medicine**
Slovakia, Denmark, Finland, Iceland, Norway, Sweden	Sitagliptin/Metformin Krka
Austria	Sitagliptin/Metformin HCS
Belgium, France	Sitagliptine/Metformine Krka
Spain	Sitagliptina/Metformina Krka
Ireland	Sitagliptin/Metformin hydrochloride Krka
Italy	Sitagliptin e Metformina Krka
Portugal	Metformina + Sitagliptina Krka

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