Package leaflet: Information for the patient

Repaglinide Krka 0.5 mg tablets
Repaglinide Krka 1 mg tablets
Repaglinide Krka 2 mg tablets

repaglinide

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 Repaglinide Krka is and what it is used for

Repaglinide Krka is an oral antidiabetic medicine containing repaglinide which helps your pancreas produce more insulin and thereby lower your blood sugar (glucose).

Type 2 diabetes is a disease in which your pancreas does not make enough insulin to control the sugar in your blood or where your body does not respond normally to the insulin it produces.

Repaglinide Krka is used to control type 2 diabetes in adults as an add-on to diet and exercise: treatment is usually started if diet, exercise and weight reduction alone have not been able to control (or lower) your blood sugar.
Repaglinide Krka can also be given with metformin, another medicine for diabetes.

Repaglinide Krka has been shown to lower the blood sugar, which helps to prevent complications from your diabetes.

2. What you need to know before you take Repaglinide Krka

Do not take Repaglinide Krka
- if you are **allergic** to repaglinide or any of the other ingredients of this medicine (listed in section 6).
- if you have **type 1 diabetes**.
- if the acid level in your blood is raised (**diabetic ketoacidosis**).
- if you have a **severe liver disease**.
- if you take **gemfibrozil** (a medicine used to lower increased fat levels in the blood).

Warning and precautions
Talk to your doctor before taking Repaglinide Krka:
- if you have **liver problems**. Repaglinide Krka is not recommended in patients with moderate liver disease. Repaglinide Krka should not be taken if you have a severe liver disease (see *Do not take Repaglinide Krka*).
- if you have **kidney problems**. Repaglinide Krka should be taken with caution.
- if you are about to have **major surgery** or you have recently suffered a **severe illness** or **infection**. At such times diabetic control may be lost.
- if you are **under 18** or **over 75 years** of age. Repaglinide Krka is not recommended. It has not been studied in these age groups.

Talk to your doctor if any of the above applies to you. Repaglinide Krka may not be suitable for you. Your doctor will advise you.

Children and adolescents

Do not take this medicine if you are under 18 years of age.

If you get a hypo (low blood sugar)

You may get a hypo (short for hypoglycaemia) if your blood sugar gets too low. This may happen:
- if you take too much Repaglinide Krka
- if you exercise more than usual
- if you take other medicines or suffer from liver or kidney problems (see other sections of 2. *What you need to know before you take Repaglinide Krka*).

The warning signs of a hypo may come on suddenly and can include: cold sweat, cool pale skin, headache, rapid heart beat, feeling sick, feeling very hungry, temporary changes in vision, drowsiness, unusual tiredness and weakness, nervousness or tremor, feeling anxious, feeling confused, difficulty in concentrating.
If your blood sugar is low or you feel a hypo coming on eat glucose tablets or a high sugar snack or drink, then rest.
When symptoms of hypoglycaemia have disappeared or when blood sugar levels are stabilised continue repaglinide treatment.
Tell people you have diabetes and that if you pass out (become unconscious) due to a hypo, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.
If severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.
If you have a hypo that makes you pass out, or a lot of hypos, talk to your doctor. The amount of Repaglinide Krka, food or exercise may need to be adjusted.

If your blood sugar gets too high

Your blood sugar may get too high (hyperglycaemia). This may happen:
- if you take too little Repaglinide Krka,
- if you have an infection or a fever,
- if you eat more than usual,
- if you exercise less than usual.

The warning signs of too high blood sugar appear gradually. They include: increased urination, feeling thirsty, dry skin and dry mouth. Talk to your doctor. The amount of Repaglinide Krka, food or exercise may need to be adjusted.

Other medicines and Repaglinide Krka

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.
You can take Repaglinide Krka with metformin, another medicine for diabetes, if your doctor prescribes it.

If you take gemfibrozil (used to lower increased fat levels in the blood) you should not take Repaglinide Krka.

Your body's response to Repaglinide Krka may change if you take other medicines, especially these:
- Monoamine oxidase inhibitors (MAOI) (used to treat depression).
- Beta blockers (used to treat high blood pressure or heart conditions).
- ACE-inhibitors (used to treat heart conditions).
- Salicylates (e.g. aspirin).
- Octreotide (used to treat cancer).
- Nonsteroidal anti-inflammatory drugs (NSAID) (a type of painkillers).
- Steroids (anabolic steroids and corticosteroids – used for anaemia or to treat inflammation).
- Oral contraceptives (birth control pills).
- Thiazides (diuretics or 'water pills').
- Danazol (used to treat breast cysts and endometriosis).
- Thyroid products (used to treat low levels of thyroid hormones).
- Sympathomimetics (used to treat asthma).
- Clarithromycin, trimethoprim, rifampicin (antibiotic medicines).
- Itraconazole, ketokonazole (antifungal medicines).
- Gemfibrozil (used to treat high blood fats).
- Ciclosporin (used to suppress the immune system).
- Deferasirox (used to reduce chronic iron overload).
- Clopidogrel (prevents blood clots).
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy).
- St.John's wort (herbal medicine).

Repaglinide Krka with alcohol

Alcohol can change the ability of Repaglinide Krka to reduce the blood sugar. Watch for signs of a hypo.

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 for advice before taking this medicine.

You should not take Repaglinide Krka if you are pregnant or you are planning to become pregnant.

You should not take Repaglinide Krka if you are breast-feeding.

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Article name.:
Prepared by:
Date: 23.10.2023

Driving and using machines

Your ability to drive or use a machine may be affected if your blood sugar is low or high. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car if you:
- have frequent hypos,
- have few or no warning signs of hypos.

Repaglinide 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 Repaglinide Krka

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

Your doctor will work out your dose.

- **The normal starting dose** is 0.5 mg before each main meal. Swallow the tablets with a glass of water immediately before or up to 30 minutes before each main meal.
- The dose may be adjusted by your doctor by up to 4 mg to be taken immediately before or up to 30 minutes before each main meal. The maximum recommended daily dose is 16 mg.

Do not take more Repaglinide Krka than your doctor has recommended.

If you take more Repaglinide Krka than you should

If you take too many tablets, your blood sugar may become too low, leading to a hypo. Please see *If you get a hypo* on what a hypo is and how to treat it.

If you forget to take Repaglinide Krka

If you miss a dose, take the next dose as usual.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Repaglinide Krka

Be aware that the desired effect is not achieved if you stop taking Repaglinide Krka. Your diabetes may get worse. If any change of your treatment is necessary contact 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.

Hypoglycaemia
The most frequent side effect is hypoglycaemia which may affect up to 1 in 10 people (see *If you get a hypo* in section 2). Hypoglycaemic reactions are generally mild/moderate but may occasionally develop into hypoglycaemic unconsciousness or coma. If this happens, medical assistance is needed immediately.

Allergy
Allergy is very rare (may affect up to 1 in 10,000 people). Symptoms such as swelling, difficulty in breathing, rapid heartbeat, feeling dizzy and sweating could be signs of anaphylactic reaction. Contact a doctor immediately.

Other side effects
Common (may affect up to 1 in 10 people):
- Stomach pain
- Diarrhoea

Rare (may affect up to 1 in 1,000 people):
- Acute coronary syndrome (but it may not be due to the medicine)

Very rare (may affect up to 1 in 10,000 people):
- Vomiting
- Constipation
- Visual disturbances
- Severe liver problems, abnormal liver function, such as increased liver enzymes in your blood.

Not known (frequency cannot be estimated from the available data)
- Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin)
- Feeling sick (nausea)

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: www.mhra.gov.uk/yellowcard 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 Repaglinide 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 blister and outer carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

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 Repaglinide Krka contains
- The active substance is repaglinide. Each tablet contains 0.5 mg, 1 mg or 2 mg repaglinide.
  The other ingredients are: microcrystalline cellulose (E460); calcium hydrogen phosphate, croscarmellose sodium; povidone K25; glycerol; magnesium stearate; meglumine; poloxamer; yellow iron oxide (E172) only in the 1 mg tablets and red iron oxide (E172) only in the 2 mg tablets. See section 2 "Repaglinide Krka contains sodium".

What Repaglinide Krka looks like and contents of the pack
The 0.5 mg tablets are white, round and biconvex with bevelled edges.
The 1 mg tablets are pale brown-yellow, round, biconvex with bevelled edges and possible darker spots.
The 2 mg tablets are pink, marbled, round, biconvex with bevelled edges and possible darker spots.

Boxes of 30, 60, 90, 120, 270 or 360 tablets in blister are available.
Not all pack sizes may be marketed.

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

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in October 2023.

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

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