Package leaflet: Information for the patient

Prasugrel Krka 5 mg film-coated tablets
Prasugrel Krka 10 mg film-coated tablets

prasugrel

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 Prasugrel Krka is and what it is used for

Prasugrel Krka, which contains the active substance prasugrel, belongs to a group of medicines called antiplatelet agents. Platelets are very small cell particles that circulate in the blood. When a blood vessel is damaged, for example if it is cut, platelets clump together to help form a blood clot (thrombus).
Therefore, platelets are essential to help stop bleeding. If clots form within a hardened blood vessel such as an artery they can be very dangerous as they can cut off the blood supply, causing a heart attack (myocardial infarction), stroke or death. Clots in arteries supplying blood to the heart may also reduce the blood supply, causing unstable angina (a severe chest pain).

Prasugrel Krka inhibits the clumping of platelets and so reduces the chance of a blood clot forming.

You have been prescribed Prasugrel Krka because you have already had a heart attack or unstable angina and you have been treated with a procedure to open blocked arteries in the heart. You may also have had one or more stents placed to keep open a blocked or narrowed artery supplying blood to the heart. Prasugrel Krka reduces the chances of you having a further heart attack or stroke or of dying from one of these atherothrombotic events. Your doctor will also give you acetylsalicylic acid (e.g. aspirin), another antiplatelet agent.

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

Do not take Prasugrel Krka
- if you are allergic to prasugrel or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor **immediately**.
- If you have a medical condition that is currently causing bleeding, such as bleeding from your stomach or intestines.
- if you have ever had a stroke or a transient ischaemic attack (TIA).
- if you have severe liver disease.

Warnings and precautions

Before you are taking Prasugrel Krka
Talk to your doctor or pharmacist before taking Prasugrel Krka.

You should tell your doctor before taking Prasugrel Krka if any of the situations mentioned below apply to you:
- If you have an increased risk of bleeding such as:
  - age of 75 years or older. Your doctor should prescribe a daily dose of 5 mg as there is a greater risk of bleeding in patients older than 75 years
  - a recent serious injury
  - recent surgery (including some dental procedures)
  - recent or recurrent bleeding from the stomach or intestines (e.g. a stomach ulcer or colon polyps)
  - body weight of less than 60 kg. Your doctor should prescribe a daily dose of 5 mg of Prasugrel Krka if you weigh less than 60 kg
  - renal (kidney) disease or moderate liver problems
  - taking certain types of medicines (see 'Taking other medicines' below)
  - planned surgery (including some dental procedures) in the next seven days. Your doctor may wish you to stop taking Prasugrel Krka temporarily due to the increased risk of bleeding
- If you have had allergic reactions (hypersensitivity) to clopidogrel or any other anti-platelet agent please tell your doctor before starting treatment with Prasugrel Krka. If you then take Prasugrel Krka and experience allergic reactions that may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath you need to tell your doctor **immediately**.

While you are taking Prasugrel Krka
You should tell your doctor immediately if you develop a medical condition called Thrombotic Thrombocytopaenic Purpura (or TTP) that includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 4 'Possible side effects').

Children and adolescents
Prasugrel Krka should not be used in children and adolescents below 18 years of age.

Other medicines and Prasugrel Krka
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, dietary supplements and herbal remedies. It is particularly important to tell your doctor if you are being treated with clopidogrel (an anti-platelet agent), warfarin (an anti-coagulant), or "non steroidal anti inflammatory drugs" for pain and fever (such as ibuprofen, naproxen, etoricoxib). If given together with prasugrel these medicines may increase the risk of bleeding.

Tell your doctor if you are taking morphine or other opioids (used to treat severe pain).

Only take other medicines while you are on prasugrel if your doctor tells you that you can.

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.
Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Prasugrel Krka.
You should use Prasugrel Krka only after discussing with your doctor the potential benefits and any potential risks to your unborn child.

Driving and using machines
Prasugrel Krka is unlikely to affect your ability to drive or use machines.

Prasugrel Krka contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Prasugrel Krka contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Prasugrel Krka

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

The recommended dose is 10 mg per day. You will start the treatment with a single dose of 60 mg.
If you weigh less than 60 kg or are more than 75 years of age, the dose is 5 mg Prasugrel Krka per day.
Your doctor will also tell you to take acetylsalicylic acid- (s)he will tell you the exact dose to take (usually between 75 mg and 325 mg daily).

You may take Prasugrel Krka with or without food. Take your dose at around the same time every day. Do not break or crush the tablet.

It is important that you tell your doctor, dentist and pharmacist, that you are taking Prasugrel Krka.

If you take more Prasugrel Krka than you should
Contact your doctor or hospital straight away, as you may be at risk of excessive bleeding. You should show the doctor your pack of Prasugrel Krka.

If you forget to take Prasugrel Krka
Do not take a double dose to make up for a forgotten dose.
If you miss your scheduled daily dose, take Prasugrel Krka when you remember. If you forget your dose for an entire day, just resume taking Prasugrel Krka at its usual dose the next day. Do not take two doses in one day.

If you stop taking Prasugrel Krka
Do not stop taking Prasugrel Krka without consulting your doctor; if you stop taking Prasugrel Krka too soon, your risk of a heart attack may be higher.

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.

Contact your doctor **immediately** if you notice any of the following:
- Sudden numbness or weakness of the arm, leg or face, especially if only on one side of the body
- sudden confusion, difficulty speaking or understanding others
- sudden difficulty in walking or loss of balance or co-ordination
- sudden dizziness or sudden severe headache with no known cause

All of the above may be signs of a stroke. Stroke is an uncommon side effect of Prasugrel Krka in patients who have never had a stroke or transient ischaemic attack (TIA).

Also contact your doctor **immediately** if you notice any of the following:

- fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice). (see section 2 'What you need to know before you take Prasugrel Krka')
- A rash, itching, or a swollen face, swollen lips/tongue, or shortness of breath. These may be signs of a severe allergic reaction (see section 2 'What you need to know before you take Prasugrel Krka').

Tell your doctor **promptly** if you notice any of the following:
- Blood in your urine
- Bleeding from your rectum, blood in your stools or black stools
- Uncontrollable bleeding, for example from a cut

All of the above may be signs of bleeding, the most common side effect with Prasugrel Krka. Although uncommon, severe bleeding can be life-threatening.

Common side effects (may affect up to 1 in 10 people)
- Bleeding in the stomach or bowels
- Bleeding from a needle puncture site
- Nose bleeds
- Skin rash
- Small red bruises on the skin (ecchymoses)
- Blood in urine
- Haematoma (bleeding under the skin at the site of an injection, or into a muscle, causing swelling)
- Low haemoglobin or red blood cell count (anaemia)
- Bruising

Uncommon side effects (may affect up to 1 in 100 people)
- Allergic reaction (rash, itching, swollen lips/tongue, or shortness of breath)
- Spontaneous bleeding from the eye, rectum, gums or in the abdomen around the internal organs
- Bleeding after surgery
- Coughing up blood
- Blood in stools

Rare side effects (may affect up to 1 in 1,000 people)
- Low blood platelet count
- Subcutaneous haematoma (bleeding under the skin causing a swelling)

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 Prasugrel 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.

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 Prasugrel Krka contains
- The active substance is prasugrel. Each film-coated tablet contains 5 mg or 10 mg prasugrel.
- The other ingredients are microcrystalline cellulose , macrogol 4000, poloxamer 188, fumaric acid – *for pH-adjustment*, croscarmellose sodium; hydrophobic colloidal silica; mannitol , magnesium stearate in the tablet core and hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, yellow iron oxide (E172) – *only for 5 mg film-coated tablets*, red iron oxide (E172) – *only for 10 mg film-coated tablets*, in film coating. See section 2 "Prasugrel Krka contains lactose and sodium".

What Prasugrel Krka looks like and contents of the pack
5 mg film-coated tablets (tablets) are pale brownish yellow, oval, biconvex, film-coated tablets, dimensions 8.5 mm x 4.5 mm.
10 mg film-coated tablets (tablets) are pink, oval, slightly biconvex, film-coated tablets, dimensions 10.5 mm x 5.5 mm.

Prasugrel Krka 5 mg film-coated tablets:
Prasugrel Krka is available in boxes containing 28, 30 and 84 film-coated tablets in blisters.

Prasugrel Krka 10 mg film-coated tablets:
Prasugrel Krka is available in boxes containing 28, 30, 84 and 90 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

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Prasugrel HCS
Belgium, Denmark, France, Ireland, Iceland, Norway, Sweden, Spain, United Kingdom (Northern Ireland)	Prasugrel Krka

This leaflet was last revised in