Package leaflet: Information for the patient

Ticagrelor Krka 90 mg film-coated tablets

ticagrelor

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 Ticagrelor Krka is and what it is used for

What Ticagrelor Krka is
Ticagrelor Krka contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines.

What Ticagrelor Krka is used for
Ticagrelor Krka in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine because you have had:
- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled).

It reduces the chances of you having another heart attack, stroke or dying from a disease related to your heart or blood vessels.

How Ticagrelor Krka works
Ticagrelor Krka affects cells called ‘platelets’ (also called thrombocytes). These very small blood cells help stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged.

However, platelets can also form clots inside diseased blood vessels in the heart and brain. This can be very dangerous because:
- the clot can cut off the blood supply completely; this can cause a heart attack (myocardial infarction) or stroke, or
- the clot can partly block the blood vessels to the heart; this reduces the blood flow to the heart and can cause chest pain which comes and goes (called ‘unstable angina’).

Ticagrelor Krka helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

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

Do not take Ticagrelor Krka if
- You are allergic to ticagrelor or any of the other ingredients of this medicine (listed in section 6).
- You are bleeding now.
- You have had a stroke caused by bleeding in the brain.
- You have severe liver disease.
- You are taking any of the following medicines:
  - ketoconazole (used to treat fungal infections)
  - clarithromycin (used to treat bacterial infections)
  - nefazodone (an antidepressant)
  - ritonavir and atazanavir (used to treat HIV infection and AIDS)

Do not take Ticagrelor Krka if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ticagrelor Krka if:
- You have an increased risk of bleeding because of:
  - a recent serious injury
  - recent surgery (including dental work, ask your dentist about this)
  - you have a condition that affects blood clotting
  - recent bleeding from your stomach or gut (such as a stomach ulcer or colon 'polyps')
- You are due to have surgery (including dental work) at any time while taking Ticagrelor Krka. This is because of the increased risk of bleeding. Your doctor may want you to stop taking this medicine 5 days prior to surgery.
- Your heart rate is abnormally low (usually lower than 60 beats per minute) and you do not already have in place a device that paces your heart (pacemaker).
- You have asthma or other lung problems or breathing difficulties.
- You develop irregular breathing patterns such as speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.
- You have had any problems with your liver or have previously had any disease which may have affected your liver.
- You have had a blood test that showed more than the usual amount of uric acid.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

If you are taking both Ticagrelor Krka and heparin:
- Your doctor may require a sample of your blood for diagnostic tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both Ticagrelor Krka and heparin, as Ticagrelor Krka may affect the diagnostic test.

Children and adolescents
Ticagrelor Krka is not recommended for children and adolescents under 18 years.

Other medicines and Ticagrelor Krka
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Ticagrelor Krka can affect the way some medicines work and some medicines can have an effect on Ticagrelor Krka.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- rosuvastatin (a medicine to treat high cholesterol), or more than 40 mg daily of either simvastatin or lovastatin (medicines used to treat high cholesterol)
- rifampicin (an antibiotic)
- phenytoin, carbamazepine and phenobarbital (used to control seizures)
- digoxin (used to treat heart failure)
- cyclosporine (used to lessen your body's defenses)
- quinidine and diltiazem (used to treat abnormal heart rhythms)

- beta blockers and verapamil (used to treat high blood pressure)
- morphine and other opioids (used to treat severe pain)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that increase your risk of bleeding:
- 'oral anticoagulants' often referred to as 'blood thinners' which include warfarin.
- Non-Steroidal Anti-Inflammatory Drugs (abbreviated as NSAIDs) often taken as painkillers such as ibuprofen and naproxen.
- Selective Serotonin Reuptake Inhibitors (abbreviated as SSRIs) taken as antidepressants such as paroxetine, sertraline and citalopram.
- other medicines such as ketoconazole (used to treat fungal infections), clarithromycin (used to treat bacterial infections), nefazodone (an antidepressant), ritonavir and atazanavir (used to treat HIV infection and AIDS), cisapride (used to treat heartburn), ergot alkaloids (used to treat migraines and headaches).

Also tell your doctor that because you are taking Ticagrelor Krka, you may have an increased risk of bleeding if your doctor gives you fibrinolytics, often called 'clot dissolvers', such as streptokinase or alteplase.

Pregnancy and breast-feeding
It is not recommended to use Ticagrelor Krka if you are pregnant or may become pregnant. Women should use appropriate contraceptive measures to avoid pregnancy while taking this medicine.

Talk to your doctor before taking this medicine if you are breast-feeding. Your doctor will discuss with you the benefits and risks of taking Ticagrelor Krka during this time.

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.

Driving and using machines
Ticagrelor Krka is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking this medicine, be careful while driving or using machines.

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

3. How to take Ticagrelor Krka

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

How much to take
- The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to you in the hospital.
- After this starting dose, the usual dose is one tablet of 90 mg twice a day for up to 12 months unless your doctor tells you differently.
- Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

Taking Ticagrelor Krka with other medicines for blood clotting
Your doctor will usually also tell you to take acetylsalicylic acid. This is a substance present in many medicines used to prevent blood clotting. Your doctor will tell you how much to take (usually between 75-150 mg daily).

How to take Ticagrelor Krka
- You can take the tablet with or without food.
- You can check when you last took a tablet of Ticagrelor Krka by looking on the blister. There is a sun (for the morning) and a moon (for the evening). This will tell you whether you have taken the dose.

If you have trouble swallowing the tablet
If you have trouble swallowing the tablet you can crush it and mix with water as follows:
- Crush the tablet to a fine powder.
- Pour the powder into half a glass of water.
- Stir and drink immediately.
- To make sure there is no medicine left, rinse the empty glass with another half a glass of water and drink it.

If you are in the hospital you may be given this tablet mixed with some water and given through a tube via the nose (nasogastric tube).

If you take more Ticagrelor Krka than you should
If you take more Ticagrelor Krka than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you. You may be at increased risk of bleeding.

If you forget to take Ticagrelor Krka
- If you forget to take a dose, just take your next dose as normal.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Ticagrelor Krka
Do not stop taking Ticagrelor Krka without talking to your doctor. Take this medicine on a regular basis and for as long as your doctor keeps prescribing it. If you stop taking Ticagrelor Krka, it may increase your chances of having another heart attack or stroke or dying from a disease related to your heart or blood vessels.

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. The following side effects may happen with this medicine:

Ticagrelor Krka affects blood clotting, so most side effects are related to bleeding. Bleeding may occur in any part of the body. Some bleeding is common (like bruising and nosebleeds). Severe bleeding is uncommon but can be life threatening.

See a doctor straight away if you notice any of the following – you may need urgent medical treatment:
- **Bleeding into the brain or inside the skull is an uncommon side effect, and may cause signs of a stroke such as:**
  - sudden numbness or weakness of your 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
  - suddenly feeling dizzy or sudden severe headache with no known cause

- **Signs of bleeding such as:**
  - bleeding that is severe or that you can not control
  - unexpected bleeding or bleeding that lasts a long time
  - pink, red or brown urine

- vomiting red blood or your vomit looks like 'coffee grounds'
- red or black stools (look like tar)
- coughing up or vomiting blood clots

- **Fainting (syncope)**
  - a temporary loss of consciousness due to sudden drop in blood flow to the brain (common)

- **Signs of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) such as:**
  - fever and purplish spots (called purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion

Discuss with your doctor if you notice any of the following:
- **Feeling short of breath - this is very common.** It might be due to your heart disease or another cause, or it might be a side effect of Ticagrelor Krka. Ticagrelor Krka-related breathlessness is generally mild and characterised as a sudden, unexpected hunger for air usually occurring at rest and may appear in the first weeks of therapy and for many may disappear. If your feeling of shortness of breath gets worse or lasts a long time, tell your doctor. Your doctor will decide if it needs treatment or further investigations.

Other possible side effects

Very common (may affect more than 1 in 10 people)
- High level of uric acid in your blood (as seen in tests)
- Bleeding caused by blood disorders

Common (may affect up to 1 in 10 people)
- Bruising
- Headache
- Feeling dizzy or like the room is spinning
- Diarrhoea or indigestion
- Feeling sick (nausea)
- Constipation
- Rash
- Itching
- Severe pain and swelling in your joints – these are signs of gout
- Feeling dizzy or light-headed, or having blurred vision – these are signs of low blood pressure
- Nosebleed
- Bleeding after surgery or from cuts (for example while shaving) and wounds more than is normal
- Bleeding from your stomach lining (ulcer)
- Bleeding gums

Uncommon (may affect up to 1 in 100 people)
- Allergic reaction – a rash, itching or a swollen face or swollen lips/tongue may be signs of an allergic reaction
- Confusion
- Visual problems caused by blood in your eye
- Vaginal bleeding that is heavier or happens at different times than your normal period (menstrual) bleeding
- Bleeding into your joints and muscles causing painful swelling
- Blood in your ear
- Internal bleeding, this may cause dizziness or light-headedness

Not known (frequency cannot be estimated from the available data)
- Abnormally low heart rate (usually lower than 60 beats per minute)

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 Ticagrelor 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.

This medicine does not require any special storage conditions.

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 Ticagrelor Krka contains
- The active substance is ticagrelor. Each film-coated tablet contains 90 mg of ticagrelor.
- The other ingredients are:
  Tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate dihydrate (E341), hypromellose 2910 (E464), croscarmellose sodium (E468), magnesium stearate (E470b).
  Film coating: hypromellose (E464), titanium dioxide (E171), talc (E553b), propylene glycol (E1520), yellow iron oxide (E172).
  See section 2 "Ticagrelor Krka contains sodium".

What Ticagrelor Krka looks like and contents of the pack
Slightly brownish-yellow, round, biconvex, film-coated tablets (tablets) engraved with mark 90 on one side.
Tablet dimensions: approximately 9 mm diameter.

Ticagrelor Krka is available in boxes containing 14, 56, 60, 100 or 168 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:

Name of the member state	Name of the medicine
Belgium, Denmark, Hungary, Finland, Iceland, Ireland, Netherland, Norway, Portugual, Spain, Sweden, United Kingdom (Northern Ireland)	Ticagrelor Krka
France	TICAGRELOR KRKA
Italy	Ticagrelor KRKA
Austria	Ticagrelor HCS

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