Package leaflet: Information for the patient

Ticagrelor Sandoz® 60 mg, filmomhulde tabletten
Ticagrelor Sandoz® 90 mg, filmomhulde tabletten

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 [Nationally completed name] is and what it is used for

What [Nationally completed name] is
[Nationally completed name] contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines.

What [Nationally completed name] is used for
[60 mg]
[Nationally completed name] 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, over a year ago.

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

[90 mg]
[Nationally completed name] 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 [Nationally completed name] works
[Nationally completed name] 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').

[Nationally completed name] 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 [Nationally completed name]

Do not take [Nationally completed name]:

- if you are allergic to ticagrelor or any of the other ingredients of this medicine (listed in section 6).
- if you are bleeding now.
- if you have had a stroke caused by bleeding in the brain.
- if you have severe liver disease.
- if 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 [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name]. 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 [Nationally completed name] 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 [Nationally completed name] and heparin, as [Nationally completed name] may affect the diagnostic test.

Children and adolescents
[Nationally completed name] is not recommended for children and adolescents under 18 years.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because [Nationally completed name] can affect the way some medicines work and some medicines can have an effect on [Nationally completed name].

Tell your doctor or pharmacist if you are taking any of the following medicines:
- rosuvastatin (a medicine to treat high cholesterol)
- 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 [Nationally completed name], 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 [Nationally completed name] 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 [Nationally completed name] 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
[Nationally completed name] 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.

[Nationally completed name] 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 [Nationally completed name]

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

How much to take

[60 mg]

- The usual dose is one tablet of 60 mg twice a day. Continue taking [Nationally completed name] as long as your doctor tells you.
- Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

[90 mg]

- 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 [Nationally completed name] 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 [Nationally completed name]

- You can take the tablet with or without food.
- You can check when you last took a tablet of [Nationally completed name] 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 [Nationally completed name] than you should
If you take more [Nationally completed name] 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 [Nationally completed name]
- 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 [Nationally completed name]
Do not stop taking [Nationally completed name] 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 [Nationally completed name], 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 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 cannot 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 [Nationally completed name]. Ticagrelor-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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 carton 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 to protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains
- The active substance is ticagrelor.
  [60 mg]
  Each film-coated tablet contains 60 mg of ticagrelor.

  [90 mg]
  Each film-coated tablet contains 90 mg of ticagrelor.

- The other ingredients are:

Tablet core: mannitol (E421), calcium hydrogen phosphate dihydrate, maize starch, starch, pregelatinised (maize), talc (E553b), sodium stearyl fumarate.

[60 mg]
Tablet film-coating: poly (vinyl alcohol) (E 1203), talc (E 553b), titanium dioxide (E 171), glycerol monocaprylocaprate, sodium laurilsulfate, iron oxide red (E 172), iron oxide black (E 172).

[90 mg]
Tablet film-coating: poly (vinyl alcohol) (E 1203), talc (E 553b), titanium dioxide (E 171), glycerol monocaprylocaprate, sodium laurilsulfate, iron oxide yellow (E 172).

What [Nationally completed name] looks like and contents of the pack

[60 mg]
Film-coated tablet (tablet): The tablets are round, biconvex, pink tablets marked with '60' on one side and plain on the other, with a diameter of 8.6 mm ± 5 %.

[90 mg]
Film-coated tablet (tablet): The tablets are round, biconvex, yellow tablets marked with '90' on one side and plain on the other, with a diameter of 9.6 mm ± 5 %.

[NL/H/4870/001-002]
[60 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 10, 14, 20, 56, 60 and 100 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 168 (3 packs of 56), 180 (3 packs of 60) and 200 (4 packs of 50) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)

[90 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 10, 14, 20, 56, 60 and 100 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 168 (3 packs of 56), 180 (3 packs of 60) and 200 (4 packs of 50) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)
- perforated unit-dosed blisters in a carton of 100x1 tablets

[NL/H/4871/001-002]
[60 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 56 and 60 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 180 (3 packs of 60) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)

[90 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 56 and 60 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 180 (3 packs of 60) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)
- perforated unit-dosed blisters in a carton of 100x1 tablets

[NL/H/4872/001-002]
[60 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 14, 56, 60 and 100 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 168 (3 packs of 56) and 180 (3 packs of 60) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)

[90 mg]
[Nationally completed name] is available in:
- standard blisters (with sun/moon symbols) in cartons of 14, 56, 60 and 100 tablets
- calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets
- multipack containing 168 (3 packs of 56) and 180 (3 packs of 60) tablets in standard blisters (with sun/moon symbols)
- multipack containing 168 (3 packs of 56) in calendar blisters (with sun/moon symbols)
- perforated unit-dosed blisters in a carton of 100x1 tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
The Netherlands

Fabrikant
PharOS MT Ltd,

HF 62X,

Hal Far Undustrial Estate,

Birzebbugia, BBG3000,

Malta

Lek Pharmaceuticals d.d.

Verovskova Ulica 57

Ljubljana 1526

Slovenia

In het register ingeschreven onder:

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland: Ticagrelor Sandoz 60 mg, 90 mg, filmomhulde Tabletten
Duitsland: Ticagrelor - 1 A Pharma 60 mg. 90 mg, Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in januari 2023