

## **Package leaflet: Information for the user**

### **Prilova 90 mg/50 mg hard capsules**

ticagrelor/acetylsalicylic acid

**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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

#### **1. What <Product name> is and what it is used for**

##### **What <Product name> is**

<Product name> contains the active substances called ticagrelor and acetylsalicylic acid. This belongs to a group of medicines called antiplatelet medicines.

##### **What <Product name> is used for**

<Product name> 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 <Product name> works**

<Product 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').

<Product 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 <Product name>**

##### **Do not take <Product name> if:**

- You are allergic to ticagrelor, acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6).
- You are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs

are often used for arthritis or rheumatism and pain.

- You have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs.
- You currently have or have ever had an ulcer in your stomach or small intestine.
- You are bleeding now.
- You have ever had the problem of your blood not clotting properly.
- You have had a stroke caused by bleeding in the brain.
- You have severe liver or kidney disease.
- You suffer from gout
- 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)
  - methotrexate in doses higher than 15 mg per week (used to treat cancer or rheumatoid arthritis)

Do not take <Product 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 <Product 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, intestinal ulcers or colon 'polyps')
- You are due to have surgery (including dental work) at any time while taking <Product 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, hay fever, nasal polyps or other chronic respiratory diseases or breathing difficulties; <Product name> may induce an asthma attack.
- 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, kidneys or heart or have previously had any disease which may have affected your liver.
- You have or have ever had problems with your stomach or small intestine.
- You have high blood pressure.
- You have ever had gout.
- You have heavy menstrual periods.
- You have had a blood test that showed more than the usual amount of uric acid.

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

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section "Possible side effects").

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since <Product name> is blood-thinning there may be an increased risk of bleeding.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of <Product name> at the same time may result in deterioration of kidney function.

If you are taking both <Product 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 <Product name> and heparin, as <Product name> may affect the diagnostic test.

### **Children and adolescents**

<Product name> is not recommended for children and adolescents under 18 years.

### **Other medicines and <Product name>**

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

- anticoagulants such as warfarin and heparin, or antiplatelet medications such as clopidogrel (medicines for the thinning of the blood/prevention of clots)
- cyclosporine, tacrolimus (used to lessen your body's defenses)
- diuretics, ACE inhibitors, beta blockers and verapamil (used to treat high blood pressure)
- digoxin (used to treat heart failure)
- 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, phenobarbital, valproic acid (used to control seizures)
- quinidine and diltiazem (used to treat abnormal heart rhythms)
- morphine and other opioids (used to treat severe pain)
- lithium (used to treat manic-depressive illness)
- NSAIDs such as ibuprofen, or steroids (used to treat pain and inflammation)
- metamizole (used to treat pain)
- uricosuric medicines such as probenecid (used to treat gout)
- acetazolamide (used to treat glaucoma)
- methotrexate; in doses lower than 15 mg per week (used to treat cancer or rheumatoid arthritis)
- sulphonylureas such as glibenclamide (used to treat diabetes)
- selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine (used to treat depression)
- corticosteroids (used as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines)
- antacids (used to treat indigestion)

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 <Product name>, you may have an increased risk of bleeding if your doctor gives you fibrinolytics, often called 'clot dissolvers', such as streptokinase or alteplase.

**<Product name> with alcohol**

Drinking alcohol when taking <Product name> may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

**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.

It is not recommended to use <Product 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 <Product name> during this time and help you decide whether to stop breast-feeding or stop taking <Product name>.

**Driving and using machines**

<Product name> is not likely to affect your ability to drive or use machines. Side effects such as dizziness or confusion have been reported, if you feel any of these side effects you should not drive or use machines.

**<Product name> contains sodium**

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

**3. How to take <Product name>**

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 capsules at the same time. This dose will usually be given to you in the hospital.
- After this starting dose, the usual dose is one capsule 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 capsule in the morning and one in the evening).

The recommended dose is the same for elderly patients. In general, <Product name> should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

**How to take <Product name>**

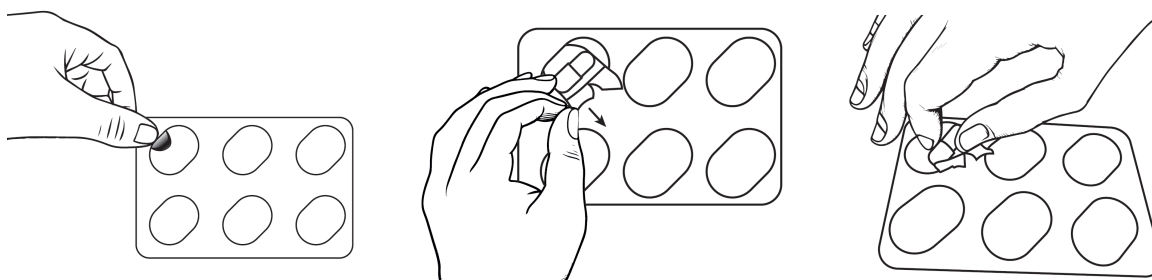
- You can take the capsule with or without food.
- Take the capsules with a glass of water.

**If you have trouble swallowing the capsule**

If you have difficulty swallowing the whole capsule, talk to your doctor about other ways to take <Product name>. The capsule can be opened, and the content can be crushed and mixed with half a glass of water immediately before you take it. The glass should be rinsed with a further half glass of water and the contents drunk.

**Instructions for opening the blisters**

Tear the aluminium foil near the edge of the pocket on the bottom side of the blister and remove the capsule from the blister pocket with caution, as depicted on the images below.



### **If you take more <Product name> than you should**

Contact your doctor immediately or go to hospital straight away if you have taken too many <Product name> capsules. Taking too much <Product name> increases the risk of bleeding.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

### **If you forget to take <Product 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 the forgotten dose.

### **If you stop taking <Product name>**

Do not stop taking <Product 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 <Product name>, it may increase your risk 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:

<Product name> 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

- **Allergic reactions are an uncommon side effect, and may cause signs such as:**
  - sudden wheezing
  - swelling of your lips/tongue, face or body
  - a rash
  - itching
  - fainting or difficulties swallowing
- **Skin reactions are a rare side effect, and may cause signs such as:**
  - reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
- **Fainting (syncope) is a common side effect, and may cause the following:**
  - a temporary loss of consciousness due to sudden drop in blood flow to the brain
- **A blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) is a side effect with an unknown frequency, and may cause signs 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 <Product name>. <Product name>-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 (vertigo)
- 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
- Increased tendency for bleeding
- Gastric or intestinal bleeding
- 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)**

- Breathing difficulty
- Confusion
- Visual problems caused by blood in your eye

- Bleeding from the reproductive system, including vaginal bleeding, blood in semen, or bleeding after menopause
- Bleeding into your joints and muscles causing painful swelling
- Blood in your ear
- Internal bleeding, this may cause dizziness or light-headedness
- Hives
- Runny noses

**Rare (may affect up to 1 in 1,000 people)**

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
- Vomiting
- Cramps in the lower respiratory tract, asthma attack
- Inflammation in the blood vessels
- Bruising with purple spots (cutaneous bleeding)
- Abnormal heavy or prolonged menstrual periods

**Not known (frequency cannot be estimated from the available data)**

- Abnormally low heart rate (usually lower than 60 beats per minute)
- Ringing in the ears (tinnitus) or reduced hearing ability
- Ulcers in stomach or small intestine and perforation
- Prolonged bleeding time
- Impaired kidney function
- Salt or water retention which may cause swelling of hands, feet, legs, stomach, breasts or face
- Impaired liver function

**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 <Product 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, bottle and carton after EXP. The expiry date refers to the last day of that month.

Aluminium-OPA/Alu/PVC blisters:

Do not store above 30°C.

HDPE bottles:

Do not store above 30°C.

Use within 6 months of first opening the bottle.

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 <Product name> contains**

- The active substances are ticagrelor and acetylsalicylic acid. Each hard capsule contains 90 mg of ticagrelor and 50 mg of acetylsalicylic acid.
- The other ingredients are:

- Capsule content: mannitol (E421), calcium hydrogen phosphate dihydrate, maize starch, starch, pregelatinised (maize), talc (E553b), sodium stearyl fumarate.
- Capsule shell: titanium dioxide (E171), purified water, gelatin
- Printing ink black: shellac (E904), iron oxide black (E172), potassium hydroxide (E525)

**What <Product name> looks like and contents of the pack**

The <Product name> 90 mg/50 mg hard capsules are hard white opaque gelatin capsules of size '00' (23.1-23.9 mm) printed with black ink '90-50 mg' on the capsule's body.

The <Product name> is available in:

- blisters in cartons of 56, 60 or multipack of 200 (4 packs of 50) hard capsules or
- perforated unit dose blisters in cartons of 28 × 1 hard capsules, 56 x 1 hard capsules or in multipack of 168 × 1 (3 packs of 56 × 1) hard capsules or
- bottles of 180 hard capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

[To be completed nationally]

**Manufacturer**

[To be completed nationally]

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

[To be completed nationally]

**This leaflet was last revised in 2025-10-01.**

[To be completed nationally]