

PACKAGE LEAFLET

Package leaflet: Information for the user

Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules rivaroxaban/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

<Product name> contains the active substances rivaroxaban and acetylsalicylic acid and belongs to a group of medicines called antithrombotic agents. Both of the active substances reduce the risk of blood clots forming, rivaroxaban works by blocking a blood clotting factor (factor Xa) and acetylsalicylic acid works by preventing platelets (a type of blood cell) in the blood from sticking together and forming clumps.

You have been given <Product name> because

- you have been diagnosed with an acute coronary syndrome (a group of conditions that includes heart attack and unstable angina, a severe type of chest pain) and have been shown to have had an increase in certain cardiac blood tests.
<Product name> reduces the risk in adults of having another heart attack or reduces the risk of dying from a disease related to your heart or your blood vessels.
<Product name> may be given to you on its own or your doctor might also tell you to take either clopidogrel or ticlopidine.

or

- you have been diagnosed with a high risk of getting a blood clot due to a coronary artery disease or peripheral artery disease which causes symptoms.
<Product name> reduces the risk in adults of getting blood clots (atherothrombotic events).
In some cases, if you get <Product name> after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take for a short while.

2. What you need to know before you take <Product name>

Do not take <Product name>

- if you are allergic to rivaroxaban, acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6)

- if you have previously had an allergic reaction (hypersensitivity) in the form of asthma attacks or in another way to certain medicines for pain, fever or inflammation (salicylates or other nonsteroidal anti-inflammatory medicines)
- if you are bleeding excessively
- if you have a disease or condition in an organ of the body that increases the risk of serious bleeding (e.g. current or recent stomach or intestinal ulcers, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you have severe kidney disease
- if you have a weakened heart (cardiac insufficiency) that is not controlled with medication
- if you are taking medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), except when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open
- if you have an acute coronary syndrome and previously had a bleeding or a blood clot in your brain (stroke)
- if you have coronary artery disease or peripheral artery disease and previously had a bleeding in your brain (stroke) or where there was a blockage of the small arteries providing blood to the brain's deep tissues (lacunar stroke) or if you had a blood clot in your brain (ischaemic, non-lacunar stroke) in the previous month
- if you have a liver disease which leads to an increased risk of bleeding
- if you are also taking 15 mg or more of methotrexate a week (see section "Other medicines and <Product name>")
- if you are pregnant or breast-feeding

Do not take <Product name> and tell your doctor if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>

- if you are hypersensitive (allergic) to other pain and anti-inflammatory medicines, other medicines for rheumatic disease, or other substances that trigger allergies (see section "Do not take <Product name>")
- if you also take nonsteroidal anti-inflammatory medicines, such as ibuprofen and naproxen (medicines for pain, fever or inflammation)
- if you have other allergies (e.g. skin reactions, itching, hives)
- if you have bronchial asthma, hay fever, swelling of the nasal mucosa (nasal polyps) or chronic respiratory disorders
- if you are also on treatment with anticoagulant medicines (e.g. coumarin derivatives, heparin - except low-dose heparin treatment)
- if you have had stomach or intestinal ulcers or gastrointestinal bleeding
- if you have impaired liver function
- if you have impaired kidney function or reduced blood flow (e.g. vascular disease in the kidneys, weakened heart muscle, reduced blood volume, major surgery, blood poisoning or increased bleeding): the risk of impaired kidney function and acute kidney failure can be further increased by acetylsalicylic acid
- prior to surgery (even minor procedures, such as tooth extractions): the tendency to bleed may be increased. Please tell your doctor or dentist if you have taken <Product name>
- if you are missing or don't have enough of an enzyme called glucose-6-phosphate dehydrogenase in your body, acetylsalicylic acid may accelerate the breakdown or decay of red blood cells or cause a certain type of anaemia. This risk may be increased by factors such as high doses, fever, or acute infections.
- if you have an increased risk of having a gout attack, an attack may be triggered from the use of low doses of acetylsalicylic acid as it reduces uric acid excretion.

<Product name> should not be used in combination with certain other medicines which reduce blood clotting such as prasugrel or ticagrelor other than clopidogrel/ticlopidine.

Take special care with <Product name>

- if you have an increased risk of bleeding, as could be the case in situations such as:
 - a problem with your kidneys, since your kidney function may affect the amount of medicine that works in your body
 - if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open (see section “Other medicines and <Product name>”)
 - bleeding disorders
 - very high blood pressure, not controlled by medical treatment
 - diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus (gullet), e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus) or tumours located in the stomach or bowels or genital tract or urinary tract
 - a problem with the blood vessels in the back of your eyes (retinopathy)
 - a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or previous bleeding from your lung
 - you are older than 75 years
 - you weigh less than 60 kg
 - you have a coronary artery disease with severe symptomatic heart failure
- if you have a prosthetic heart valve
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.

If any of the above apply to you, tell your doctor before you take <Product name>. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If you need to have an operation

- it is very important to take <Product name> before and after the operation exactly at the times you have been told by your doctor.
- If your operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
 - it is very important to take <Product name> before and after the injection or removal of the catheter exactly at the times you have been told by your doctor
 - tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

Children and adolescents

<Product name> 2.5 mg/50 mg hard capsules are **not recommended for people under 18 years of age**. There is not enough information on its use in children and adolescents.

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, before using **<Product name>**. If you use **<Product name>** regularly, tell your doctor before taking any other medicine.

- If you are taking:
 - some medicines for fungal infections (e.g. fluconazole, itraconazole, voriconazole,

- posaconazole), unless they are only applied to the skin
- ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol)
- some medicines for bacterial infections (e.g. clarithromycin, erythromycin)
- some anti-viral medicines for HIV / AIDS (e.g. ritonavir)
- other medicines to reduce blood clotting (e.g. enoxaparin, clopidogrel, coumarin, heparin or vitamin K antagonists such as warfarin and acenocoumarol, prasugrel and ticagrelor (see sections "Do not take <Product name>" and "Warnings and Precautions"))
- other platelet aggregation inhibitors (medicines that stop platelets from sticking together and clumping (e.g. ticlopidine, clopidogrel))
- anti-inflammatory and pain relieving medicines (e.g. naproxen) and medicines for rheumatic diseases containing salicylic acid (see section "Do not take <Product name>")
- dronedarone, a medicine to treat abnormal heart beat
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs))
- medicines that dissolve blood clots (thrombolytic)
- medicines containing cortisone or cortisone-like substances (except products applied to the skin or cortisone replacement therapy for Addison's disease) medicines that lower blood glucose (antidiabetic drugs) e.g. insulin, tolbutamide, glibenclamide))
- digoxin, a medicine for strengthening the heart
- methotrexate, a medicine for treating cancer and certain rheumatic diseases (see section "Do not take <Product name>")
- some medicines to prevent rejection of organ after transplantation (cyclosporin, tacrolimus)
- valproic acid, an agent for treating brain seizures (epilepsy)
- metamizole, a medicine for treating pain and fever
- some medicines that increase urine output (e.g. spironolactone, canrenoate, furosemide)
- some antihypertensive medicines (especially ACE inhibitors)
- some medicines for gout that increase uric acid excretion (e.g. probenecid, benzbromarone)
- some nonsteroidal anti-inflammatory drugs (except acetylsalicylic acid) e.g. ibuprofen and naproxen))
- some medicines for treatment of epilepsy (phenytoin, carbamazepine, phenobarbital)
- St John's Wort (*Hypericum perforatum*), a herbal product used for depression
- rifampicin, an antibiotic

If any of the above apply to you, tell your doctor before taking <Product name>, because the effect of <Product name> may be increased or reduced. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, he may also use a preventative ulcer treatment.

<Product name> with alcohol

Drinking alcohol when taking <Product name> increases the risk of gastrointestinal ulcers and bleeding.

Pregnancy and breast-feeding

Do not take <Product name> if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking <Product name>. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

<Product name> may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4, “Possible side effects”). You should not drive, ride a bicycle or use any tools or machines if you are affected by these symptoms.

<Product name> 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 medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say 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 recommended dose is one <Product name> capsule twice a day. Take <Product name> around the same time every day (for example, one capsule in the morning and one in the evening).

If you get <Product name> after an acute coronary syndrome, your doctor may tell you to also take clopidogrel or ticlopidine.

If you get <Product name> after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take a short while.

Your doctor will tell you how much of these to take (usually a daily dose of either 75 mg clopidogrel or a standard daily dose of ticlopidine).

Method of administration

This medicine can be taken with or without food.

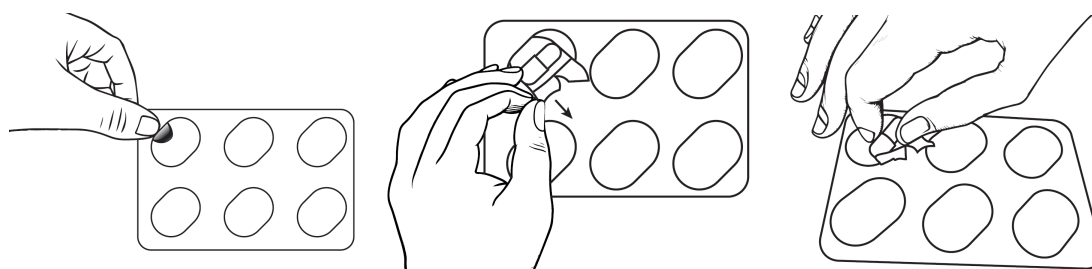
Take the capsules with plenty of water.

If you have difficulty swallowing the whole capsule, talk to your doctor about other ways to take <Product name>. The capsule may be opened, and the content may be crushed and mixed with water immediately before you take it.

If necessary, your doctor may also give you the crushed content of the capsule through a stomach tube.

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.



When to start <Product name>

Treatment with <Product name> after an acute coronary syndrome should be started as soon as possible after stabilisation of the acute coronary syndrome, at the earliest 24 hours after admission to hospital and at the time when parenteral (via injection) anticoagulation therapy would normally be stopped.

Your doctor will tell you when to start treatment with <Product name> if you have been diagnosed with coronary artery disease or peripheral artery disease.

Your doctor will decide how long you must continue treatment.

If you take more <Product name> than you should

Contact your doctor immediately if you have taken too many <Product name> capsules. Taking too much <Product name> increases the risk of bleeding.

Symptoms of overdose may include decreased blood glucose levels, skin rashes, gastrointestinal bleeding, breathing difficulties, ringing in the ears, nausea, vomiting, impaired vision and hearing, headache, dizziness, confusion, shaking, shortness of breath, sweating, dehydration, fever and coma.

If you forget to take <Product name>

Do not take a double dose to make up for a forgotten dose. If you miss a dose, take your next dose at the usual time.

If you stop taking <Product name>

Take <Product name> on a regular basis and for as long as your doctor keeps prescribing it.

Do not stop taking <Product name> without talking to your doctor first. If you stop taking this medicine, it may increase your risk of having another heart attack or stroke or dying from a disease related to your heart or your 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, <Product name> can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, <Product name> may cause bleeding which may potentially be life threatening. Excessive bleeding may lead to a sudden drop in blood pressure (shock). In some cases the bleeding may not be obvious.

Tell your doctor immediately if you experience any of the following side effects:**• Signs of bleeding**

- bleeding into the brain or inside the skull (symptoms can include headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness. A serious medical emergency. Seek medical attention immediately!)
- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris

Your doctor may decide to keep you under closer observation or change the treatment.

• Signs of severe skin reactions

- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a drug reaction that causes rash, fever, inflammation of internal organs, blood

- abnormalities and systemic illness (DRESS syndrome).
- very rare to severe, feverish skin eruptions with involvement of the mucosal membranes (erythema multiforme).

The frequency of these side effects is very rare (up to 1 in 10,000 people).

- **Signs of severe allergic reactions**

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties; sudden drop in blood pressure.

The frequencies of severe allergic reactions are very rare (anaphylactic reactions, including anaphylactic shock; may affect up to 1 in 10,000 people) and uncommon (angioedema and allergic oedema; may affect up to 1 in 100 people).

Overall list of possible side effects

Common (may affect up to 1 in 10 people)

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nose bleed, bleeding in the gum
- bleeding into the eye (including bleeding from the whites of the eyes)
- bleeding into tissue or a cavity of the body (haematoma, bruising)
- coughing up blood
- bleeding from the skin or under the skin
- bleeding following an operation
- oozing of blood or fluid from surgical wound
- swelling in the limbs
- pain in the limbs
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever
- stomach ache, heartburn, indigestion, nausea, vomiting, feeling or being sick, constipation, abdominal pain, diarrhoea
- low blood pressure (symptoms may be feeling dizzy or fainting when standing up)
- decreased general strength and energy (weakness, tiredness), headache, dizziness
- rash, itchy skin
- blood tests may show an increase in some liver enzymes

Uncommon (may affect up to 1 in 100 people)

- bleeding into the brain or inside the skull (see above, signs of bleeding)
- bleeding into a joint causing pain and swelling
- gastric or intestinal bleeding
- anaemia
- thrombocytopenia (low number of platelets, which are cells that help blood to clot)
- allergic reactions, including allergic skin reactions
- impaired function of the liver (may be seen in tests performed by your doctor)
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- gastric or intestinal ulcers
- gastrointestinal inflammation
- fainting
- feeling unwell
- faster heartbeat
- dry mouth
- skin reactions

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

- severe bleeding, e.g. bleeding in the brain
- bleeding, such as nose bleeds, bleeding gums, skin bleeding, bleeding in the urinary tracts and genital organs or bleeding into a muscle, with potentially prolonged bleeding time
- faster destruction of red blood cells and a certain type of anaemia in patients who are missing or don't have enough of an enzyme called glucose-6-phosphate dehydrogenase in their body
- allergic (hypersensitivity) reactions of the skin, respiratory tracts, gastrointestinal tract and cardiovascular system, especially in asthmatics. The following symptoms may occur: e.g. a drop in blood pressure, attacks of shortness of breath, inflammation of the nasal mucosa, nasal congestion, allergic shock, swelling of the face, tongue and larynx (Quincke's oedema)
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver incl. liver injury)
- yellowing of the skin and eye (jaundice)
- localised swelling
- collection of blood (haematoma) in the groin as a complication of the cardiac procedure where a catheter is inserted in your leg artery (pseudoaneurysm)

Very rare (may affect up to 1 in 10,000 people)

- accumulation of eosinophils, a type of white granulocytic blood cells that cause inflammation in the lung (eosinophilic pneumonia)
- increased liver function values
- decreased blood glucose levels (hypoglycaemia)
- impaired kidney function and acute kidney failure
- reduction of uric acid excretion (this can trigger an attack of gout in patients who are at risk)

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

- kidney failure after a severe bleeding
- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy)
- increased pressure within muscles of the legs or arms after a bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after a bleeding)
- membranes may develop in the intestinal cavity possibly with subsequent narrowing (if the intestinal mucosa was previously damaged)

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 carton, bottle or blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

HDPE bottles:

Use within 2 months after first opening of 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 protect the environment.

6. Contents of the pack and other information

What <Product name> contains

- The active substances are rivaroxaban and acetylsalicylic acid. Each hard capsule contains 2.5 mg of rivaroxaban and 50 mg of acetylsalicylic acid.
- The other ingredients are:
Capsule content: lactose, cellulose, microcrystalline (E460), sodium laurilsulfate, poloxamer, croscarmellose sodium, magnesium stearate (E470b).
Capsule shell: titanium dioxide (E171), water, purified, gelatin.

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

<Product name> 2.5 mg/50 mg hard capsules are white opaque hard gelatin capsules of size '00' (23.5 ± 0.4 mm) containing two white to off-white, round, biconvex tablets, blank on both sides and white crystalline powder.

They come

- in blisters in unit packs of 56 hard capsules or in multipacks of 196 (4 packs of 49) hard capsules or
- in bottles of 56 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 2025-11-17.