Package leaflet: Information for the user Rivaroxaban 10 mg Film-coated Tablets

Rivaroxaban

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even
- 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.

- 1. What Rivaroxaban 10 mg is and what it is used for
- 2. What you need to know before you take Rivaroxaban 10 mg
- 3. How to take Rivaroxaban 10 mg
- 4. Possible side effects

1. What Rivaroxaban 10 mg is and what it is used for

- prevent blood clots in the veins after a hip or knee replacement operation. Your doctor has prescribed
- treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of

Rivaroxaban 10 mg belongs to a group of medicines called antithrombotic agents. It works by blocking a

2. What you need to know before you take Rivaroxaban 10 mg

Do not take Rivaroxaban 10 mg

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine (listed in section 6)
- if you are bleeding excessively
- (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you are taking medicines to prevent blood clotthing (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 are pregnant or breast feeding

Talk to your doctor or pharmacist before taking Rivaroxaban 10 mg

- if you have an increased risk of bleeding, as could be the case in situations such as:

- moderate or severe kidney disease, since your kidney function may affect the amount of
- 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 Rivaroxaban
- bleeding disorders
- very high blood pressure, not controlled by medical treatment
- 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 tumors 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
- 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
- procedure to remove the blood clot from your lungs is planned

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

- 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 Rivaroxaban 10 mg exactly at the times you have been told by your
- 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.

Rivaroxaban 10 mg is not recommended for people under 18 years of age. There is not enough information on its use in children and adolescents.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. including medicines obtained without prescription.

- If you are taking:

- posaconazole), unless they are only applied to the skin
- cortisol)
- Some medicines for bacterial infections (e.g. clarithromycin, erythromycin)
- other medicines to reduce blood clotting (e.g. enoxaparin, clopidogrel or vitamin K antagonists
- anti-inflammatory and pain relieving medicines (e.g. naproxen or acetylsalicylic acid)
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or
- serotonin norepinephrine reuptake inhibitors (SNRIs))

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

If you are taking:

- some medicines for treatment of epilepsy (phenytoin, carbamazepine, phenobarbital)

Rivaroxaban 10 mg may be reduced. Your doctor will decide, if you should be treated with Rivaroxaban 10 mg and if you should be kept under closer observation.

Do not take Rivaroxaban 10 mg 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 Rivaroxaban 10 mg If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Rivaroxaban 10 mg 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.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

Rivaroxaban contains sodium

"sodium free".

3. How to take Rivaroxaban 10 mg

you are not sure.

How much to take

- The recommended dose is one tablet Rivaroxaban (10 mg) once a
- After at least 6 months blood clot treatment, the recommended dose is either one 10 mg tablet once

Swallow the tablet preferably with water.

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.

if their signs of illness are the same as yours.

What is in this leaflet

5. How to store Rivaroxaban 10 mg

6. Contents of the pack and other information

Rivaroxaban 10 mg contains the active substance rivaroxaban and is used in adults to

this medicine for you because after an operation you are at an increased risk of getting blood clots.

your legs and/or lungs.

blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

- if you have a disease or condition in an organ of the body that increases the risk of serious bleeding
- if you have a liver disease which leads to an increased risk of bleeding
- Do not take Rivaroxaban 10 mg and tell your doctor if any of these apply to you.

Warnings and precautions

Take special care with Rivaroxaban 10 mg

- medicine that works in your body
- 10 mg")
- - diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the
- previous bleeding from your lung
- if your doctor determines that your blood pressure is unstable or another treatment or surgical

If any of the above apply to you, tell your doctor before you take Rivaroxaban 10 mg. Your doctor will

- It is very important to take Rivaroxaban 10 mg before and after the operation exactly at the

Children and adolescents

Other medicines and Rivaroxaban 10 mg

- some medicines for fungal infections (e.g. ketoconazole, itraconazole, voriconazole,
- ketoconazole tablets (used to treat Cushing's syndrome when the body produces an excess of
- specific anti-viral medicines for HIV / AIDS (e.g. ritonavir)
- such as warfarin and acenocoumarol)
- dronedarone, a medicine to treat abnormal heart beat

If any of the above apply to you, tell your doctor before taking Rivaroxaban 10 mg because the effect of Rivaroxaban 10 mg may be increased. Your doctor will decide, if you should be treated with this medicine

use a preventative ulcer treatment.

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 Rivaroxaban 10 mg, because the effect of

Pregnancy and breast feeding

Driving and using machines

Rivaroxaban 10 mg contains lactose

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if

To prevent blood clots in the veins after a hip or knee replacement operation

To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs, and

for preventing blood clots from re-occurring a day or one 20 mg tablet once a day. Your doctor has prescribed you Rivaroxaban 10 mg once a day.

Rivaroxaban 10 mg can be taken with or without food.

Rivaroxaban 10 mg should not be crushed prior to administration and should not be administered through a stomach tube.

When to take Rivaroxaban 10 mg

Take the tablet every day until your doctor tells you to stop. Try to take the tablet at the same time every day to help you to remember it.

Your doctor will decide how long you must continue treatment.

To prevent blood clots in the veins after a hip or knee replacement operation:

Take the first tablet 6 - 10 hours after your operation.

If you have had a major hip operation you will usually take the tablets for 5 weeks. If you have had a major knee operation you will usually take the tablets for 2 weeks.

Each HDPE bottle conatains a desiccant canister corresponding to a 'drying agent'. It is to protect the tablets from moisture. Do not swallow this desiccant container. If you do accidentally take a desiccant container, talk to your doctor straight away. It should not harm you.

If you take more Rivaroxaban 10 mg than you should
Contact your doctor immediately if you have taken too many Rivaroxaban 10 mg tablets. Taking too much Rivaroxaban 10 mg increases the risk of bleeding.

If you forget to take Rivaroxaban 10 mg If you have missed a dose, take it as soon as you remember. Take the next tablet on the following day and

then carry on taking a tablet once a day as normal.

Do not take a double dose to make up for a forgotten tablet. If you stop taking Rivaroxaban 10 mg Do not stop taking Rivaroxaban 10 mg without talking to your doctor first, because Rivaroxaban 10 mg

prevents the development of a serious condition. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Rivaroxaban 10 mg can cause side effects, although not everybody gets them. Like other similar medicines to reduce the formation of blood clots, Rivaroxaban 10 mg 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).

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)

- bleeding from the skin or under the skin

coughing up blood

- swelling in the limbs

- bleeding following an operation - oozing of blood or fluid from surgical wound
- pain in the limbs - impaired function of the kidneys (may be seen in tests performed by your doctor)

- low blood pressure (symptoms may be feeling dizzy or fainting when standing up)

- stomach ache, indigestion, feeling or being sick, constipation, diarrhoea
- 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
- 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 - fainting

- bleeding into a muscle

- feeling unwell - faster heartbeat - dry mouth
- hives **Rare** (may affect up to 1 in 1,000 people):
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver incl. liver injury) - vellowing of the skin and eve (jaundice) - localised swelling

- collection of blood (haemotoma) 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 eosinophilic granulocytes, a subgroup of white blood cells that cause inflammation in the lungs (eosinophilic pneumonia)

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

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) 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 Yellow Card Scheme:

- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to

www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App Sore. By reporting side effects you can help provide more information on the safety of this medicine.

- kidnev failure after a severe bleeding

5. How to store Rivaroxaban 10 mg 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, the bottle or on each blister after EXP. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.

Shelf life after 1st opening: 100 days. 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

- The other ingredients are:

What Rivaroxaban 10 mg contains - The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban.

sodium laurilsulfate, magnesium stearate. Tablet film coat: macrogol, hypromellose, titanium dioxide (E171), iron oxide red (E172) What Rivaroxaban 10 mg looks like and contents of the pack

Rivaroxaban 10 mg Film-coated Tablets Light red, round biconvex tablets marked with "A1" on one side and plain on the other side.

OPA/AI/PVC/AI blister or Alu/PVC/PVdC blister: Blister packs with 5, 10, 30, 98 and 100 film-coated tablets.

Manufacturer

HDPE bottle:

HDPE bottle containing 30 or 100 tablets with child resistant or continuous thread closure with induction

Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose,

Each bottle contains a silica gel dessicant in a separate canister. The silica gel desiccant must be kept in the bottle to protect the tablets from moisture until all tablets have been taken. It should not be swallowed. Not all pack sizes may be marketed.

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This leaflet was last revised in September 2023.

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