

ZYROXABAN FILM COATED TABLET

Rivaroxaban (10 mg)

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What Zyroxaban is used for

Zyroxaban contains the active substance rivaroxaban and is used in adults to

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

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

How Zyroxaban works

Zyroxaban belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

Before you use Zyroxaban

- When you must not use it

Do not take Zyroxaban

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine
- 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. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- 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 a liver disease which leads to an increased risk of bleeding
- if you are pregnant or breast-feeding

Do not take Zyroxaban and tell your doctor if any of these apply to you.

- Before you start to use it

Warnings and precautions

Talk to your doctor or pharmacist before taking Zyroxaban.

Take special care with Zyroxaban

- 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 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 "Taking other medicines")
- 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)

- 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
- 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 your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.

If any of the above apply to you, tell your doctor before you take Zyroxaban. 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 Zyroxaban 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 Zyroxaban 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.

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Children and adolescents

Zyroxaban tablets are not recommended for people under 18 years of age. There is not enough information on its use in children and adolescents.

Pregnancy and breast-feeding

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

Zyroxaban contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- Taking other medicines

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

- 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

or vitamin K antagonists such as warfarin and acenocoumarol)

- anti-inflammatory and pain relieving medicines (e.g. naproxen or acetylsalicylic acid)
- dronedarone, a medicine to treat abnormal heartbeat
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs))

If any of the above apply to you, tell your doctor before taking Zyroxaban, because the effect of Zyroxaban may be increased. 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.

- If you are taking

- 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 Zyroxaban, because the effect of Zyroxaban may be reduced. Your doctor will decide, if you should be treated with Zyroxaban and if you should be kept under closer observation.

How to use Zyroxaban

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 use

- To prevent blood clots in the veins after a hip or knee replacement operation: the recommended dose is one tablet Zyroxaban 10 mg once a day.

Swallow the tablet preferably with water. Zyroxaban can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Zyroxaban. The tablet maybe crushed and mixed with water or apple puree immediately before you take it. If necessary, your doctor may also give you the crushed Zyroxaban tablet through a stomach tube.

- When to use it

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.

- How long to use it

Keep taking Zyroxaban every day for as long as your doctor tells you. Do not stop taking Zyroxaban without talking

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

- If you forget to use it

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 use too much (overdose)

Contact your doctor immediately if you have taken too many Zyroxaban tablets. Taking too much Zyroxaban increases the risk of bleeding.

While you are using Zyroxaban

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Zyroxaban.

- Things you must not do

- Do not stop taking the medicines without consulting your doctor.
- Do not use Zyroxaban after the expiry date which is stated on the carton and blister
- Do not give this medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines

Zyroxaban may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 'Side effects'). You should not drive or use machines if you are affected by these symptoms.

Side Effects

Like all medicines, Zyroxaban can cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), Zyroxaban 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.

Possible side effects which maybe a sign of bleeding. Tell your doctor immediately if you experience any of the following side effects:

- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris, which may be signs of bleeding.

Your doctor may decide to keep you under closer observation or change how you should be treated.

Possible side effects which maybe a sign of severe skin reaction. Tell your doctor immediately if you experience skin reactions such as:

- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens- Johnson syndrome/toxic epidermal necrolysis). The frequency of this side effect is very rare.
- a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome). The frequency of this side effect is very rare.

Possible side effects which may be a sign of severe allergic reactions. Tell your doctor immediately if you experience any of the following side effects:

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties; sudden drop in blood pressure. The frequencies of these side effects are very rare (anaphylactic reactions, including anaphylactic shock) and uncommon (angioedema and allergic oedema).

Overall list of possible side effects

Common

- 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
- stomachache, indigestion, feeling or being sick, constipation, diarrhoea
- low blood pressure (symptoms may be feeling dizzy or fainting when

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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

- bleeding into the brain or inside the skull
- 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 (maybe 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
- feeling unwell
- faster heartbeat
- dry mouth
- hives

Rare

- bleeding into a muscle
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver including 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)

Not known

- kidney failure after a severe bleeding
- 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zyroxaban

- Storage

Keep this medicine out of the sight and reach of children.

Store at temperatures not exceeding 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Zyroxaban 10 mg film coated tablets are red biconvex round film coated tablets debossed with "10" on one side and plain on the other side.

- Ingredients

- Active ingredient

Rivaroxaban 10 mg

- Inactive ingredients

Tablet core:

- Microcrystalline cellulose
- Lactose monohydrate
- Croscarmellose sodium

- Hypromellose
- Sodium lauryl sulfate
- Magnesium stearate

Film coat:

- Hypromellose 2910
- Polyethylene Glycol 3350
- Iron Oxide Red
- Titanium Dioxide

- MAL number:

MAL25106012ACZ

Manufacturer

Changzhou Pharmaceutical Factory
No. 518 Laodong East Road,
Changzhou, Jiangsu Province, China.

Product Registration Holder

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