

RIVASON 10 (Rivaroxaban Film Coated Tablets 10mg)

Rivaroxaban (10mg film-coated tablets)

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What Rivason 10 is used for

Rivason 10 is used in adult to:

- prevent blood clots in the veins after a hip or knee replacement operation.
- 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 your legs and/or lungs.

How Rivason 10 work

Rivason 10 contains the active substance rivaroxaban and 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 Rivason 10

-When you must not take it

Do not take Rivason 10:

- 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

-Before you start to take it

Take special care with Rivason 10:

- if you have an increased risk of bleeding, as could be the case in situations such as:
 - 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 Rivason 10.

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 any operation or 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 Rivason 10 before and after the operation 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

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

-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,

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erythromycin)

- some anti-viral medicines for HIV/AIDS (e.g. ritonavir)
- 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 Rivason 10, because the effect of Rivason 10 may be increased.

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 Rivason 10, because the effect of Rivason 10 may be reduced.

Your doctor will decide, if you should be treated with Rivason 10 and if you should be kept under closer observation.

Pregnancy and breast-feeding

Do not take Rivason 10 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 Rivason 10. If you become pregnant while you are taking this medicine, tell your

doctor immediately, who will decide how you should be treated.

Rivason 10 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.

How to take Rivason 10

-How much to take

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

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

- the recommended dose is one tablet Rivason 10mg once a day

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:

- The recommended dose is one tablet Rivason 15mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet Rivason 20mg once a day.
- After at least 6 months blood clot treatment your doctor may decide to continue treatment with either one 10 mg tablet once a day or one 20 mg tablet once a day.
- If you have kidney problems and take one tablet Rivason 20mg once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet Rivason 15mg once a day if the risk for bleeding is greater than the risk for having another blood clot.

Swallow the tablet preferably with water. Rivason 10 can be taken with or without food. If you have difficulty swallowing the tablet whole, talk to your doctor about other

ways to take Rivason. The tablet may be crushed and mixed with water or apple puree immediately before you take it. The crushed Rivason tablet also may be given through a stomach tube.

-When and how long to take it

Take the tablet(s) every day until your doctor tells you to stop.

Try to take the tablet(s) at the same time every day to help you to remember it.

Your doctor will decide how long you must continue treatment.

-If you forget to take 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 take too much (overdose)

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

While you are using Rivason 10

-Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Rivason 10.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor or pharmacist. Do not give Rivason 10 to anyone else, even if they have the same condition as you.

-Things to be careful of

Driving and using machines
Rivason 10 may cause dizziness or fainting (see section "Side effects"). You should not drive

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or use machines if you are affected by these symptoms.

Side Effects

Like other anti-blood clot medicines, Rivason 10 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 may be 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.

Possible side effects which may be 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).
- a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome).

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.

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, blood in the urine, heavy menstrual bleeding, nosebleed, 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 and pain in the limbs
- impaired function of the kidneys
- fever
- stomachache, indigestion, feeling or being sick, constipation, 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:

- 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
- 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 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:

- accumulation of eosinophils, a type of white granulocytic blood cells that cause inflammation in the lung (eosinophilic pneumonia)

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 of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Rivason 10

-Storage

Keep this medicine out of the sight and reach of children. Store at a temperature not exceeding 30° C. Do not use this medicine after the expiry date which is stated

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on the label. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

-Disposal

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.

Product Description

-What it looks like

Light-red, round shaped, biconvex, film-coated tablets, debossed with "C5" on one side and plain on other side.

-Ingredients

Active Ingredient
Each tablet contains
Rivaroxaban 10mg

Inactive ingredients
Microcrystalline cellulose,
lactose monohydrate,
croscarmellose sodium,
hypromellose, sodium lauryl sulfate, colloidal anhydrous silica, magnesium stearate, opadry pink (04F540031), purified water.

-MAL Number

MAL24106025AZ

Manufacturer

Unison Pharmaceuticals Pvt Ltd
Unit III C-7,8,9 Steel Town,
Opp. Nova Petrochemicals,
Village Moraiya, Sanand,
Ahmedabad, Gujarat 382213,
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Product Registration Holder

Celestemal Pharma Sdn Bhd
3 Jalan 19/1, 46300 Petaling
Jaya, Selangor, Malaysia

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09/06/2025

Serial Number

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