

RIROXATOR 15MG/20MG FILM COATED TABLETS

Rivaroxaban 15 mg and 20 mg tablets

What is in this leaflet

1. What RIROXATOR is used for
2. How RIROXATOR works
3. Before you use RIROXATOR
4. How to use RIROXATOR
5. While you are using it
6. Side effects
7. Storage and disposal of RIROXATOR
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What RIROXATOR is used for

Prevents blood clots in brain (stroke) and other blood vessels in your body if you have a irregular form of heart rhythm called non-valvular atrial fibrillation.

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 blood clots of your legs and/or lungs.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Riroxator for another reason.

Riroxator is a prescription medicine. It should only be used in adults under medical supervision.

How RIROXATOR works

The active substance is rivaroxaban. It belongs to a group of medicines called antithrombotic. It works by inhibiting the blood clotting protein called Factor Xa, thus reducing the tendency of blood to form clots.

Before you use RIROXATOR

-When you must not take it

Do not take Riroxator:

- 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 breastfeeding

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

Pregnancy and lactation

Do not use this medicine if you are pregnant or intend to become pregnant.

Women should use a reliable contraceptive while taking Riroxator.

Do not use Riroxator if you are breastfeeding. It is not known whether rivaroxaban passes into human breast milk.

- Before you start to use RIROXATOR

Talk to your doctor or pharmacist before taking Riroxator. Riroxator 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 tablet, that is to say essentially "sodiumfree" Take special care with Riroxator

- 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 medicine")

- 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 Riroxator. 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 Riroxator 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)

RIROXATOR 15MG/20MG FILM COATED TABLETS

Rivaroxaban 15 mg and 20 mg tablets

- it is very important to take Riroxator 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

Riroxator 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 any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Riroxator because its effect may be increased.

Some medicines and Riroxator may interfere with each other. These include:

- other medicines to reduce blood clotting e.g. enoxaparin, clopidogrel or warfarin
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)).

These medicines may be affected by Riroxator, may increase the effect of Riroxator or may affect how well Riroxator works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Riroxator.

Tell your doctor if you are taking anti-inflammatory and pain-relieving medicines e.g. naproxen, or medicines used for the protection of heart disease e.g. acetylsalicylic acid (aspirin).

Your doctor may decide to keep you 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:

- medicines for treatment for epilepsy (phenytoin, carbamazepine)
- St John's Wort, a herbal product used for depression
- Rifampicin, an antibiotic

Tell your doctor before taking Riroxator because its effect may be reduced.

How to use RIROXATOR

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pharmacist label, ask your doctor or pharmacist for help.

- How much to take

To prevent blood clots in brain (stroke) and other blood vessels. The usual dose is one 20 mg tablet once a day. If your kidneys are not working properly, your doctor may reduce your dose to one 15 mg tablet once a day. Riroxator 15mg and 20 mg tablets are to be taken with food.

To treat blood clots in your legs and clots in your lungs and for preventing blood clots from re-occurring. The usual dose is one 15 mg tablet TWICE daily for the first three weeks. After the first three weeks, take 20 mg ONCE daily. Riroxator 15mg and 20 mg tablets are to be taken with food. Swallow the tablets preferably with water.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Riroxator. The tablet may be crushed and mixed with water or apple puree immediately before you take it.

If necessary, the crushed Riroxator tablet may be given to you through a stomach tube.

After giving the crushed Riroxator tablet via the stomach tube, you or your carer should flush the tube with water. If you are taking the 15 or 20mg Riroxator tablet, you should be fed via the stomach tube straight after your dose of Riroxator.

- When to take it

For prevention of stroke or treatment or prevention of blood clots in your legs and/or lungs, take the tablet(s) every day until your doctor tells you to stop.

Your doctor will decide how long you must continue your treatment.

If your heartbeat needs to be restored to normal by a procedure called cardioversion, take Riroxator according to your doctor's instructions.

If you need a procedure to treat blocked blood vessels in your heart (called a percutaneous coronary intervention – PCI with an insertion of a stent), the dose may be changed by your doctor.

Your doctor will advise you about any changes to the amount of Riroxator you should take.

It is important that you follow instructions from your doctor and not to miss or stop taking your medicine or lower the dosage without checking with your doctor. Riroxator has been prescribed to you by your doctor to treat and/or prevent a serious medical condition.

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

- How long to use it

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

Your doctor will decide how long you must continue treatment.

- If you forget to take it

If you are taking one 15 mg, or one 20 mg tablet ONCE a day: If you have missed a dose, take it as soon as you remember. Do not take more than one tablet in a single day to make up for a forgotten dose.

Take the next tablet on the following day and then carry on taking a tablet once a day as normal. Do not take a

RIROXATOR 15MG/20MG FILM COATED TABLETS

Rivaroxaban 15 mg and 20 mg tablets

double dose to make up for a forgotten tablet.

If you are taking one 15 mg tablet TWICE a day and have missed a dose, take it as soon as you remember. If you forget to take a dose; you can take two 15 mg tablets at the same time to get a total dose of 30 mg in one day. The following day onwards, you should take one 15 mg tablet twice a day as normal, until required.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much Riroxator increases the risk of bleeding.

While you are using it

- Things you must do

If you are about to be started on any new medicine reminds your doctor and pharmacist that you are taking Riroxator.

Take Riroxator exactly as your doctor has prescribed.

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

Tell your doctor if you need to have a surgical or dental procedure.

Tell your doctor that you are using Riroxator, if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

Tell your doctor if other medications are prescribed to you during the course of therapy with Riroxator.

If you become pregnant while you are taking Riroxator, immediately tell your doctor.

- Things you must not do

Do not take Riroxator to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor first because Riroxator treats and prevents serious conditions.

- Things to be careful of

Driving and using machine

Riroxator 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, Riroxator can cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), Riroxator 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.

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

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). 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), 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 in the limbs
- pain in the limbs
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever

RIROXATOR 15MG/20MG FILM COATED TABLETS

Rivaroxaban 15 mg and 20 mg tablets

- 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 (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
- 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)

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)

Other side effects not listed above may also occur in some people. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my

[Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of RIROXATOR

- Storage

Store below 30°C.

- Disposal

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

Product Description

- What it looks like

RIROXATOR 15 MG FILM COATED TABLETS

Round, red, biconvex film-coated tablets having “A2” debossed on one side and plain on other side.

RIROXATOR 20 MG FILM COATED TABLETS

Dark red colored, oval shaped, biconvex film coated tablets with “A3” debossed on one side and plain on other side.

Packaging:

Blisters in cartons of 30 film coated tablets.

- Ingredients

Active ingredient:

- Rivaroxaban.

Inactive ingredients:

- Hypromellose 2910.
- Lactose Monohydrate (Pharmatose DCL-11).

- Croscarmellose Sodium.
- Microcrystalline Cellulose (PH 102).
- Magnesium Stearate.
- Sodium Lauryl Sulphate.
- Purified water.
- Opadry Brown 03F565079 (for 15mg).
- Opadry II Brown 85F565098 (for 20mg).

- MAL number

RIROXATOR 15 MG FILM COATED TABLETS

MALxxxxxxxxxx

RIROXATOR 20 MG FILM COATED TABLETS

MALxxxxxxxxxx

Manufacturer

Torrent Pharmaceuticals Ltd. – Indrad Plant.
Near Indrad Village, Taluka Kadi, District Mehsana, Gujarat 382721, INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

Date of Revision

13/09/2022

Serial Number

NPRA (R2) 22/049