

RIVAXORED (RIVAROXABAN TABLETS)

Rivaroxaban (15 mg & 20 mg)

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What Rivaxored is used for

Rivaxored is used in adults to

- prevent blood clots in brain (stroke) and other blood vessels in your body if you have a form of irregular 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 in the blood vessels of your legs and/or lungs.

Rivaxored is used in children and adolescents below 18 years and with a body weight of 30 kg or more to:

- treat blood clots and prevent reoccurrence of blood clots in the veins or in the blood vessels of the lungs, following initial treatment of at least 5 days with injectable medicines used to treat blood clots.

How Rivaxored works

Rivaxored 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 Rivaxored

- *When you must not use it*

Do not take this medicine if:

- you are allergic to rivaroxaban or any of the other ingredients of this medicine.
- you are bleeding excessively.
- 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).

- 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.
- you have a liver disease which leads to an increased risk of bleeding.
- you are pregnant or breast-feeding.

Do not take Rivaxored 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 Rivaxored.

Take special care with Rivaxored

- 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 Rivaxored. Your doctor will decide, if you should be treated with this medicine or if you should be kept under closer observation.

If you need to have an operation

- it is very important to take Rivaxored 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 Rivaxored 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

Rivaxored tablets are not recommended for children with a body weight below 30kg. There is not enough information on its use in children and adolescents in the adult indications.

Pregnancy and lactation

Do not use Rivaxored if you are pregnant or breast-feeding. If there is a chance that you could become

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pregnant, use a reliable contraceptive while you are taking Rivaxored. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Rivaxored contains lactose and sodium

Rivaxored 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.

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

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 Rivaxored, because the effect of Rivaxored may be increased. Your doctor will decide, if you should be treated with this medicine or 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 Rivaxored, because the effect of Rivaxored may be reduced. Your doctor will decide, if you should be treated with Rivaxored or if you should be kept under closer observation.

How to use Rivaxored

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- *How much to use*

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

Adults

To prevent blood clots in brain (stroke) and other blood vessels in your body.

- The recommended dose is one tablet Rivaxored 20 mg once a day. If you have kidney problems, the dose may be reduced to one tablet Rivaxored 15 mg 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

Rivaxored 15 mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet Rivaxored 20 mg 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 Rivaxored 20 mg once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet Rivaxored 15 mg once a day if the risk for bleeding is greater than the risk for having another blood clot.

Children and adolescents

The dose of Rivaxored depends on the body weight and will be calculated by the doctor.

- The recommended dose for children and adolescents with a body weight between 30 kg and less than 50 kg is one Rivaxored 15 mg tablet once a day.
- The recommended dose for children and adolescents with a body weight of 50 kg or more is one Rivaxored 20 mg tablet once a day.

Take each Rivaxored dose with a drink (e.g. water or juice) during a meal. Take the tablets every day at approximately the same time. Consider setting an alarm to remind you. For parents or caregivers: please observe the child to ensure the full dose is taken.

As the Rivaxored dose is based on body weight it is important to keep scheduled doctor's visits because the dose may need to be adjusted as the weight changes. Never adjust the dose of Rivaxored by yourself. The doctor will adjust the dose if necessary.

Do not split the tablet in an attempt to provide a fraction of a tablet dose. If a lower dose is required, please use alternative presentations such as granules for oral suspension. For children and adolescents who are unable to swallow tablets whole, please use other suitable pharmaceutical forms

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such as granules for oral suspension.

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

If you spit up the dose or vomit

- less than 30 minutes after you have taken Rivaxored, take a new dose.
- more than 30 minutes after you have taken Rivaxored, do not take a new dose. In this case, take the next Rivaxored dose at the usual time.

Contact the doctor if you repeatedly spit up the dose or vomit after taking Rivaxored.

- 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.

- How long to use it

Do not stop taking Rivaxored without talking to your doctor first, because Rivaxored treats and prevents serious conditions. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

Adults, children, and adolescents:

If you are taking one 20 mg tablet or one 15 mg tablet once a day and 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 one tablet once a day.

Adults:

If you are taking one 15 mg tablet twice a day and have missed a dose, take it as soon as you remember. Do not take more than two 15 mg tablets in a single day. If you forget to take a dose you can

take two 15 mg tablets at the same time to get a total of two tablets (30 mg) on one day. On the following day you should carry on taking one 15 mg tablet twice a day

- If you use 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 use 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 Rivaxored increases the risk of bleeding.

While you are using Rivaxored

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Rivaxored.

Tell your doctor immediately if you become pregnant while using this medication.

Take Rivaxored only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Rivaxored to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Rivaxored 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, Rivaxored can

cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), Rivaxored 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.

Overall list of possible side effects

Common

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- bleeding into the eye (including bleeding from the whites of the eyes)
- low blood pressure (pressure symptoms may be feeling dizzy or fainting when standing up)
- bleeding into tissue or a cavity of the body (haematoma)
- nose bleed
- coughing up blood
- bleeding in the gum
- bleeding in the stomach or bowel
- stomach ache
- indigestion
- nausea
- constipation
- diarrhoea
- vomit
- blood tests may show an increase in

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- some liver enzymes
- itchy skin
- rash
- bruise
- bleeding from the skin or under the skin
- pain in the limbs
- urogenital bleeding (including blood in the urine and heavy menstrual bleeding)
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever
- swelling in the legs, feet, arms or hands.
- weakness and tiredness
- bleeding following an operation
- oozing of blood or fluid from surgical wound

Uncommon

- low number of platelets in blood
- abnormally high number of platelets in blood
- allergic reactions, including allergic skin reactions
- deep swelling under the skin (angioedema)
- Swelling caused by an allergic reaction (allergic oedema)
- fainting
- faster heartbeat
- dry mouth
- hives
- bleeding into a joint causing pain and swelling
- feeling unwell

Rare

- yellowing of the skin and eye (jaundice)
- localised swelling

Very rare

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

- including anaphylactic shock).
- 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).

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and disposal of Rivaxored

- Storage
Store below 30°

Keep out of the reach and sight of children

- Disposal
Medicines should not be disposed 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

RIVAXORED (Rivaroxaban 15mg):
A red coloured, round, biconvex film coated tablet, engraved with '15' on one side of the tablet and plain on other side.

RIVAXORED (Rivaroxaban 20mg):
A dark red coloured, round, biconvex film coated tablet, engraved with '20' on one side of the tablet and plain on other side.

- Ingredients

- Active ingredient
RIVAXORED (Rivaroxaban 15mg):
Rivaroxaban 15mg
RIVAXORED (Rivaroxaban 20mg):
Rivaxored 20mg; Rivaroxaban 20mg

- Inactive ingredients

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Cellulose Microcrystalline, Lactose Monohydrate, Croscarmellose Sodium, Hypromellose 5 CPS, Sodium Lauryl Sulfate, Magnesium Stearate and Opadry Brown 04F565014.

RIVAXORED (Rivaroxaban Tablets 20mg)

Cellulose Microcrystalline, Lactose Monohydrate, Croscarmellose Sodium, Hypromellose 5 CPS, Sodium Lauryl Sulfate, Magnesium Stearate and Opadry Red 04F550002.

- MAL number

RIVAXORED (Rivaroxaban Tablets 15mg)

MAL21116017AZ

RIVAXORED (Rivaroxaban Tablets 20mg)

MAL21056023AZ

Manufacturers

- Packed and released by

GoodScience Sdn Bhd
No. 7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya, 48020 Rawang,
Selangor, Malaysia.

- Manufactured by

Dr. Reddy's Laboratories Limited
Formulation Tech Ops-II,
Survey No 42p, 43, 44p, 45p, 46p, 53, 54
& 83, Bachupally Village,
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Product Registration Holder

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