

RIVALTO TABLETS

Consumer Medication Information Leaflet (RiMUP)

Rivaroxaban 15 mg and 20 mg

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What RIVALTO Is Used For

RIVALTO is used in adults to:

- prevention of 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.

RIVALTO is used in children and adolescents below 18 years and with a body weight of 30kg 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 RIVALTO 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 RIVALTO

– When you must not take it

Do not take RIVALTO:

- 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 RIVALTO 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 RIVALTO.

Do not use RIVALTO if you are breast-feeding. It is not known whether rivaroxaban passes into human breast milk.

– Before you start to use RIVALTO

Talk to your doctor or pharmacist before taking RIVALTO.

RIVALTO 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 “sodium free”

Take special care with RIVALTO

- 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 RIVALTO. 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 RIVALTO 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 RIVALTO 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

RIVALTO 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.

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– 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 RIVALTO because its effect may be increased.

Some medicines and RIVALTO 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 RIVALTO, may increase the effect of RIVALTO or may affect how well RIVALTO 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 RIVALTO.

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 RIVALTO, because its effect may be reduced.

How to use RIVALTO

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

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 RIVALTO 20 mg once a day. If you have kidney problems, the dose may be reduced to one tablet RIVALTO 15mg 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 RIVALTO 15 mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet RIVALTO 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 RIVALTO 20 mg once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet RIVALTO 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 RIVALTO 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 RIVALTO 15 mg tablet once a day.
- The recommended dose for children and adolescents with a body weight of 50 kg or more is one RIVALTO 20 mg tablet once a day.

Take each RIVALTO 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 RIVALTO 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 RIVALTO 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 such as granules for oral suspension.

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

If you spit up the dose or vomit:

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

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

– 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 RIVALTO 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 RIVALTO you should take.

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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. RIVALTO 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

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 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 RIVALTO 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 RIVALTO.

Take RIVALTO exactly as your doctor has prescribed.

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

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

Tell your doctor that you are using RIVALTO, 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 RIVALTO.

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

– Things you must not do

Do not take RIVALTO 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 RIVALTO treats and prevents serious conditions.

– Things to be careful of

Driving and using machine

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

Like other similar medicines (antithrombotic agents), RIVALTO 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 (StevensJohnson 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

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(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 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)

Side effects in children and adolescents

In general, the side effects observed in

children and adolescents treated with RIVALTO were similar in type to those observed in adults and were primarily mild to moderate in severity.

Side effects that were observed more often in children and adolescents:

Very common (may affect more than 1 in 10 people)

- headache
- fever
- nose bleeding
- vomiting

Common (may affect up to 1 in 10 people)

- raised heartbeat
- blood tests may show an increase in bilirubin (bile pigment)
- thrombocytopenia (low number of platelets which are cells that help blood to clot)
- heavy menstrual bleeding

Uncommon (may affect up to 1 in 100 people)

- blood tests may show an increase in a subcategory of bilirubin (direct bilirubin, bile pigment)

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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of RIVALTO

– Storage

Keep your tablets in their blister pack until it is time to take them. If you take the tablets out of the box or blister pack, they may not keep well.

Store the tablets in a cool dry place where the temperature stays below 30 °C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep out of the reach and sight of children. A locked cupboard at least one

and a half meters above the ground is a good place to store medicines.

– 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

RIVALTO 15 mg film-coated tablets are Round, brown, film-coated biconvex tablets debossed with '504' on one side and plain on the other side. It is packed in blister packs in cartons of 30 tablets.

RIVALTO 20 mg film-coated tablets are Triangle shaped, brown, film-coated tablets debossed with '505' on one side and plain on the other side. It is packed in blister packs in cartons of 30 tablets.

– Ingredients

Active ingredient per tablet:

- RIVALTO 15 mg contains 15 mg rivaroxaban
- RIVALTO 20 mg contains 20 mg rivaroxaban

Inactive ingredients:

- Lactose Monohydrate
- Croscarmellose Sodium
- Microcrystalline cellulose
- Hypromellose
- Sodium Lauryl Sulphate
- Colloidal Silicon Dioxide
- Magnesium Stearate
- Opadry
- Hypromellose
- Titanium Dioxide
- Macrogol
- Iron Oxide Red
- Ferrosoferric Oxide

– MAL number

RIVALTO 15mg Tablet:
MAL21116019AZ

RIVALTO 20mg Tablet:
MAL21116018AZ

Manufacturer

Alembic Pharmaceuticals Limited
(Formulation Division),
At- Panelav, Tal- Halol,
City: Panelav,
Dist: Panchmahal, Gujarat
State, India.

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Product Registration Holder

Genpharma Sdn. Bhd.
Lot 5016, Jalan Teratai,
5½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia.

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