Package leaflet: Information for the user

Rivaroxaban Teva GmbH 15 mg film-coated tablets
Rivaroxaban Teva GmbH 20 mg film-coated tablets

rivaroxaban

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rivaroxaban Teva GmbH is and what it is used for
2. What you need to know before you take Rivaroxaban Teva GmbH
3. How to take Rivaroxaban Teva GmbH
4. Possible side effects
5. How to store Rivaroxaban Teva GmbH
6. Contents of the pack and other information

1. What Rivaroxaban Teva GmbH is and what it is used for

Rivaroxaban Teva GmbH contains the active substance rivaroxaban and 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.

Rivaroxaban Teva GmbH 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 re-occurrence 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.

Rivaroxaban Teva GmbH 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.

2. What you need to know before you take Rivaroxaban Teva GmbH

Do not take Rivaroxaban Teva GmbH:
- if you are allergic to rivaroxaban or any of the other ingredients of this medicine (listed in section 6)
- 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 Rivaroxaban Teva GmbH and tell your doctor if any of these apply to you.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rivaroxaban Teva GmbH.

Take special care with Rivaroxaban Teva GmbH
- if you have an increased risk of bleeding, as could be the case in situations such as:
    - severe kidney disease for adults, and moderate or severe kidney disease for children and adolescents, 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 "Other medicines and Rivaroxaban Teva GmbH")
    - 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) or tumours located in the stomach or bowels or genital tract or urinary tract
    - 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 Rivaroxaban Teva GmbH. 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 Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH 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
Rivaroxaban tablets are **not recommended for children with a body weight below 30 kg.**
There is not enough information on the use of rivaroxaban in children and adolescents in the adult indications.

Other medicines and Rivaroxaban Teva GmbH
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 heart beat
- 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 Rivaroxaban Teva GmbH, because the effect of Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH, because the effect of Rivaroxaban Teva GmbH may be reduced. Your doctor will decide, if you should be treated with Rivaroxaban Teva GmbH and if you should be kept under closer observation.

Pregnancy and breast-feeding
Do not take Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines
Rivaroxaban Teva GmbH may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4, "Possible side effects"). You should not drive, ride a bicycle or use any tools or machines if you are affected by these symptoms.

Rivaroxaban Teva GmbH contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially 'sodium-free'.

3. How to take Rivaroxaban Teva GmbH

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

You must take Rivaroxaban Teva GmbH together with a meal.
Swallow the tablet(s) preferably with water.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Rivaroxaban Teva GmbH. The tablet may be crushed and mixed with water or apple puree immediately before you take it. This mixture should be immediately followed by food.

If necessary, your doctor may also give you the crushed Rivaroxaban Teva GmbH tablet through a stomach tube.

How much to take

Adults
- To prevent blood clots in brain (stroke) and other blood vessels in your body:
  The recommended dose is one tablet Rivaroxaban Teva GmbH 20 mg once a day.
  If you have kidney problems, the dose may be reduced to one tablet Rivaroxaban Teva GmbH 15 mg once a day.

  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), there is limited evidence to reduce the dose to one tablet rivaroxaban 15 mg once a day (or to one tablet rivaroxaban 10 mg once a day in case your kidneys are not working properly) in addition to an antiplatelet medicine such as clopidogrel.

- 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 Rivaroxaban Teva GmbH 15 mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH 20 mg once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH 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 **Rivaroxaban Teva GmbH 15 mg tablet** once a day.
- The recommended dose for children and adolescents with a **body weight of 50 kg or more** is one **Rivaroxaban Teva GmbH 20 mg tablet** once a day.

Take each Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH 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 Rivaroxaban Teva GmbH 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 other products are available that are formulated as granules for oral suspension.
For children and adolescents who are unable to swallow tablets whole, please use other products that are formulated as granules for oral suspension.
If the oral suspension is not available, you may crush the Rivaroxaban Teva GmbH tablet and mix with water or apple puree immediately before taking. Take some food after taking this mixture. If necessary, your doctor may also give the crushed Rivaroxaban Teva GmbH tablet through a stomach tube.

If you spit up the dose or vomit
- less than 30 minutes after you have taken Rivaroxaban Teva GmbH, take a new dose.

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

Contact the doctor if you repeatedly spit up the dose or vomit after taking Rivaroxaban Teva GmbH.

When to take Rivaroxaban Teva GmbH
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.

To prevent blood clots in the brain (stroke) and other blood vessels in your body:
If your heart beat needs to be restored to normal by a procedure called cardioversion, take Rivaroxaban Teva GmbH at the times your doctor tells you.

If you forget to take Rivaroxaban Teva GmbH
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 more Rivaroxaban Teva GmbH than you should
Contact your doctor immediately if you have taken too many Rivaroxaban Teva GmbH tablets. Taking too much Rivaroxaban Teva GmbH increases the risk of bleeding.

If you stop taking Rivaroxaban Teva GmbH
Do not stop taking Rivaroxaban Teva GmbH without talking to your doctor first, because Rivaroxaban Teva GmbH treats and prevents serious conditions.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Rivaroxaban Teva GmbH can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, Rivaroxaban Teva GmbH 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.

Tell your doctor immediately if you or the child experience any of the following side effects:
Signs of bleeding
- bleeding into the brain or inside the skull (symptoms can include headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness. A serious medical emergency. Seek medical attention immediately!)
- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris.

Your doctor may decide to keep you under closer observation or change the treatment.

Signs of severe skin reactions
- 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, blood abnormalities and systemic illness (DRESS syndrome).

The frequency of these side effects is very rare (up to 1 in 10,000 people).

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

The frequencies of severe allergic reactions are very rare (anaphylactic reactions, including anaphylactic shock; may affect up to 1 in 10,000 people) and uncommon (angioedema and allergic oedema; may affect up to 1 in 100 people).

Overall list of possible side effects found in adults, children and adolescents

Common (may affect up to 1 in 10 people)
- 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
- stomach ache, 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 (may affect up to 1 in 100 people)
- bleeding into the brain or inside the skull (see above, signs of bleeding)
- 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 (may affect up to 1 in 1,000 people)
- 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 (may affect up to 1 in 10,000 people)
- accumulation of eosinophils, a type of white granulocytic blood cells that cause inflammation in the lung (eosinophilic pneumonia)

Not known (frequency cannot be estimated from the available data)
- kidney failure after a severe bleeding
- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy)
- 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 rivaroxaban 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)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rivaroxaban Teva GmbH

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

Do not use this medicine after the expiry date which is stated on the carton and blister or bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Crushed tablets
Crushed tablets are stable in water or apple puree for up to 4 hours.

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.

6. Contents of the pack and other information

What Rivaroxaban Teva GmbH contains

- The active substance is rivaroxaban. Each tablet contains 15 mg or 20 mg rivaroxaban.
- The other ingredients are:
  Tablet core: Mannitol, sodium laurilsulfate, cellulose microcrystalline, hypromellose, croscarmellose sodium, magnesium stearate.
  Film-coating for 15 mg: Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol, talc (E553b), iron oxide yellow (E172), iron oxide red(E172).
  Film-coating for 20 mg: Poly(vinyl alcohol) (E1203), macrogol, talc (E553b), iron oxide red (E172).

What Rivaroxaban Teva GmbH looks like and contents of the pack

Rivaroxaban Teva GmbH 15 mg film-coated tablets are orange, round (approximately 6.5 mm in diameter) film-coated tablets, debossed with “T” on one side and “8X” on the other side.
Rivaroxaban Teva GmbH 20 mg film-coated tablets are red, round (approximately 7.6 mm in diameter) film-coated tablets, debossed with “T” on one side and “9X” on the other side.

Rivaroxaban Teva GmbH 15 mg: is available in perforated unit-dose blisters containing 10x1, 14x1, 28x1, 30x1, 42x1, 90x1, 98x1, 100x1 or 112x1 film-coated tablets or perforated blisters containing 10, 14, 28, 30, 42, 90, 98, 100 and 112 film-coated tablets or packs containing one or two bottles each containing 100 film-coated tablets or bottles containing 200 film-coated tablets.

Rivaroxaban Teva GmbH 20 mg: in unit-dose blisters containing 10x1, 14x1, 28x1, 30x1, 90x1, 98x1, 100x1 or 112x1 film-coated tablets or perforated blisters containing 10, 14, 28, 30, 42, 90, 98, 100 and 112 film-coated tablets packs containing one or two bottles each containing 100 film-coated tablets or bottles containing 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the EEA under the following names:

Austria	Rivaroxaban ratiopharm GmbH
Belgium	Rivaroxaban Teva
Czech Republic	Rivaroxaban Teva GmbH

Germany	Rivaroxaban-ratiopharm
Denmark	Rivaroxaban Teva GmbH
Estonia	Rivaroxaban TevaPharm
Greece	Rivaroxaban/Teva
Spain	Rivaroxaban Tevagen
Finland	Rivaratio
France	RIVAROXABAN TEVA SANTE
Croatia	Rivaroksaban Teva GmbH
Hungary	Rivaroxaban Teva GmbH
Ireland	Rivaroxaban Teva GmbH
Iceland	Rivaroxaban Teva GmbH
Italy	RIVAROXABAN TEVA ITALIA
Lithuania	Rivaroxaban TevaPharm
Latvia	Rivaroxaban TevaPharm
Luxembourg	Rivaroxaban Teva
Netherlands	Rivaroxaban Teva GmbH
Norway	Rivaroxaban Teva GmbH
Portugal	Rivaroxabano ratiopharm
Romania	Rivaroxaban Teva Pharmaceuticals
Sweden	Rivaroxaban Teva GmbH
Slovakia	Rivaroxaban Teva GmbH

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