Package leaflet: Information for the user

Rivaroxaban Clonmel 2.5 mg film-coated tablet
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 Clonmel is and what it is used for
2. What you need to know before you take Rivaroxaban Clonmel
3. How to take Rivaroxaban Clonmel
4. Possible side effects
5. How to store Rivaroxaban Clonmel
6. Contents of the pack and other information

1. What Rivaroxaban Clonmel is and what it is used for
You have been given Rivaroxaban Clonmel because
- you have been diagnosed with an acute coronary syndrome (a group of conditions that includes heart attack and unstable angina, a severe type of chest pain) and have been shown to have had an increase in certain cardiac blood tests.
  Rivaroxaban Clonmel reduces the risk in adults of having another heart attack or reduces the risk of dying from a disease related to your heart or your blood vessels.
  Rivaroxaban Clonmel will not be given to you on its own. Your doctor will also tell you to take either:
  - acetylsalicylic acid or
  - acetylsalicylic acid plus clopidogrel or ticlopidine

or
- you have been diagnosed with a high risk of getting a blood clot due to a coronary artery disease or peripheral artery disease which causes symptoms.
  Rivaroxaban Clonmel reduces the risk in adults of getting blot clots (atherothrombotic events).
  Rivaroxaban Clonmel will not be given to you on its own. Your doctor will also tell you to take acetylsalicylic acid.
  In some cases, if you get Rivaroxaban Clonmel after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take in addition to acetylsalicylic acid for a short while.

Rivaroxaban Clonmel 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.

2. What you need to know before you take Rivaroxaban Clonmel
DO NOT take Rivaroxaban Clonmel
- 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 an acute coronary syndrome and previously had a bleeding or a blood clot in your brain (stroke)
- if you have coronary artery disease or peripheral artery disease and previously had a bleeding in your brain (stroke) or where there was a blockage of the small arteries providing blood to the brain's deep tissues (lacunar stroke) or if you had a blood clot in your brain (ischaemic, non-lacunar stroke) in the previous month
- 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 Clonmel and tell your doctor if any of these apply to you.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rivaroxaban Clonmel.
Rivaroxaban Clonmel should not be used in combination with certain other medicines which reduce blood clotting such as prasugrel or ticagrelor other than acetylsalicylic acid and clopidogrel/ticlopidine.

Take special care with Rivaroxaban Clonmel
- 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 "Other medicines and Rivaroxaban Clonmel")
  - 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
  - you are older than 75 years
  - you weigh less than 60 kg
  - you have a coronary artery disease with severe symptomatic heart failure
- 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 any of the above apply to you, tell your doctor before you take Rivaroxaban Clonmel. 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 Clonmel 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 Clonmel 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 Clonmel 2.5 mg tablets are **not recommended for people under 18 years of age**. There

is not enough information on their use in children and adolescents.

Other medicines and Rivaroxaban Clonmel
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, prasugrel and ticagrelor (see section "Warnings and Precautions"))
  - 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 Rivaroxaban Clonmel, because the effect of Rivaroxaban Clonmel 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 Clonmel, because the effect of Rivaroxaban Clonmel may be reduced. Your doctor will decide, if you should be treated with Rivaroxaban Clonmel and if you should be kept under closer observation.

Pregnancy and breast-feeding
Do not take Rivaroxaban Clonmel 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 Clonmel. 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 Clonmel 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 Clonmel 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.

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

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

How much to take
The recommended dose is one 2.5 mg tablet twice a day. Take Rivaroxaban Clonmel around the same time every day (for example, one tablet in the morning and one in the evening). This medicine can be taken with or without food.

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

Rivaroxaban Clonmel will not be given to you on its own.
Your doctor will also tell you to take acetylsalicylic acid. If you get Rivaroxaban Clonmel after an acute coronary syndrome, your doctor may tell you to also take clopidogrel or ticlopidine.
If you get Rivaroxaban Clonmel after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take in addition to acetylsalicylic acid for a short while.

Your doctor will tell you how much of these to take (usually between 75 to 100 mg acetylsalicylic acid daily or a daily dose of 75 to 100 mg acetylsalicylic acid plus a daily dose of either 75 mg clopidogrel or a standard daily dose of ticlopidine).

When to start Rivaroxaban Clonmel
Treatment with Rivaroxaban Clonmel after an acute coronary syndrome should be started as soon as possible after stabilisation of the acute coronary syndrome, at the earliest 24 hours after admission to hospital and at the time when parenteral (via injection) anticoagulation therapy would normally be stopped.
Your doctor will tell you when to start treatment with Rivaroxaban Clonmel if you have been diagnosed with coronary artery disease or peripheral artery disease.
Your doctor will decide how long you must continue treatment.

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

If you forget to take Rivaroxaban Clonmel
Do not take a double dose to make up for a missed dose. If you miss a dose, take your next dose at the usual time.

If you stop taking Rivaroxaban Clonmel
Take Rivaroxaban Clonmel on a regular basis and for as long as your doctor keeps prescribing it.

Do not stop taking Rivaroxaban Clonmel without talking to your doctor first. If you stop taking this medicine, it may increase your risk of having another heart attack or stroke or dying from a disease related to your heart or your blood vessels.

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

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, Rivaroxaban Clonmel 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 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

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)

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 Clonmel
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 on each blister 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 Clonmel contains
The active substance is rivaroxaban.
One film-coated tablet contains 2.5 mg rivaroxaban.

The other ingredients are:

Tablet core
Cellulose, microcrystalline
Lactose monohydrate
Povidone

Starch, pregelatinised
Crospovidone
Sodium lauryl sulfate
Magnesium stearate

Film-coat
Hypromellose E464
Titanium dioxide E171
Macrogol 4000 E1521
Iron oxide yellow E172

What Rivaroxaban Clonmel looks like and contents of the pack
Light yellow, round, biconvex film-coated tablets with a diameter of approximately 6 mm.

Available in blister or unit dose blister packs containing 10, 10x1, 14, 14x1, 15, 15x1, 20, 20x1, 28, 28x1, 30, 30x1, 42, 42x1, 56, 56x1, 60, 60x1, 98, 98x1, 100, 100x1, 168, 168x1, 196 and 196x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria:	Rivaroxaban STADA 2,5 mg Filmtabletten
Belgium:	Rivaroxaban EG 2,5 mg filmomhulde tabletten
Denmark:	Rivaroxaban STADA 2,5 mg filmovertrukne tabletter
Estonia:	Rivaroxaban STADA
Finland:	Rivaroxaban STADA 2,5 mg kalvopäällysteiset tabletit
France:	RIVAROXABAN EG 2,5 mg, comprimé pelliculé
Germany:	Rivaroxaban AL 2,5 mg Filmtabletten
Greece:	Rivaroxaban / Stada
Hungary:	Rivaroxaban STADA 2,5 mg filmtabletta
Iceland:	Rivaroxaban STADA 2,5 mg filmuhúðaðar töflur
Ireland:	Rivaroxaban Clonmel 2.5 mg film-coated tablets
Latvia:	Rivaroxaban Stada 2,5 mg apvalkotās tabletes
Lithuania:	Rivaroxaban STADA 2,5 mg plėvele dengtos tabletės
Luxembourg:	Rivaroxaban EG 2.5mg comprimés pelliculés
Netherlands:	Rivaroxaban CF 2,5 mg, filmomhulde tabletten
Norway:	Rivaroxaban STADA
Portugal:	Rivaroxabano Ciclum
Romania:	Rivaroxaban STADA 2.5 mg comprimate filmate
Spain:	Rivaroxaban STADA 2,5 mg comprimidos recubiertos con película EFG
Sweden:	Rivaroxaban STADA 2,5 mg filmdragerade tabletter

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