Rivaroxaban ▼

10 mg, 15 mg and 20 mg Film-coated tablets

PATIENT ALERT CARD

What should I know about Rivaroxaban?

- Rivaroxaban thins the blood,which prevents you from getting dangerous blood clots.
- Rivaroxaban must be taken exactly as prescribed by your doctor. To ensure optimal protection from blood clots, **never skip a dose.**
- You must not stop taking rivaroxaban without first talking to your doctor as your risk of blood clots may increase.
- Tell your health care provider about any other medicines you are currently taking, took recently or intend to start taking, before you start Rivaroxaban.
- Tell your healthcare provider that you are taking Rivaroxaban before any surgery or invasive procedure.

When should I seek advice from my health care provider?

When taking a blood thinner such as Rivaroxaban it is important to beaware of its possible side effects. Bleeding is the most common side effect. Do not start taking rivaroxaban if you know you are at risk of bleeding, without first discussing this with your doctor. Tell you health care provider straight away if you have any signs or symptoms of bleeding such as the following:

- pain
- swelling or discomfort
- headache, dizziness or weakness
- unusual bruising, nosebleeds, bleeding of gums, cuts that take a long time to stop bleeding
- menstrual flow or vaginal bleeding that is heavier than normal
- blood in your urine which may be pink or brown, red or black stools
- coughing up blood, or vomiting blood or material that looks like coffee grounds

How do I take Rivaroxaban?

To ensure optimal protection, Rivaroxaban

- 10 mg can be taken with or without food
- 15 mg must be taken with food
- 20 mg must be taken with food

Keep this card with you at all times

Present this card to every physician or dentist prior to treatment

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Rivaroxaban to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Sandoz Pharmaceuticals d.d. Verovškova Ulica 57, SI-1000 Ljubljana, Slovenia

Local Distributor: VJ Salomone Pharma Limited – Upper Cross Road, Marsa, MRS 1542, Malta

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm - **and download the required material with the latest date.**

I am under anticoagulation treatment with rivaroxaban

Name: _____

Adress:

_____

_____

_____

_____

Birth date: _____

Other Medications / Conditions:

_____

_____

_____

_____

_____

Weight: _____

In case of emergency, please notify:

Doctor's name: _____

Doctor's Phone: _____

Doctor's Stamp: _____

Please also notify:

Name: _____

Phone: _____

Relationship: _____

Information for health care providers:

- International Normalized Ratio (INR) values should not be used as they are not a dependable measure of the anticoagulant activity of Rivaroxaban.

This educational material is a part of the conditions of the Marketing Authorisation