



# Safety information card for patients under anticoagulant treatment with Rivaroxaban Dexcel<sup>®</sup>

**Rivaroxaban Dexcel<sup>®</sup> 2.5 mg**

**Rivaroxaban Dexcel<sup>®</sup> 10 mg**

**Rivaroxaban Dexcel<sup>®</sup> 15 mg**

**Rivaroxaban Dexcel<sup>®</sup> 20 mg**

Carry this card with you at all times.  
Present this card to every doctor or dentist at the beginning of the visit.

**The patient carrying this card is under anticoagulant treatment Rivaroxaban Dexcel**

Name \_\_\_\_\_

Address \_\_\_\_\_

Date of birth \_\_\_\_\_ Weight \_\_\_\_\_

Information regarding concomitant diseases and medications \_\_\_\_\_

**Information in case of emergency**

**In case of emergency, please inform the treating doctor** \_\_\_\_\_

Phone \_\_\_\_\_

**Please also inform:**

Name \_\_\_\_\_ Relationship \_\_\_\_\_

Phone \_\_\_\_\_

Emergency phone number (clinic/first aid) \_\_\_\_\_

## Information regarding the use of the medicine

Treatment start date \_\_\_\_\_

Indication \_\_\_\_\_

Dosage and administration regimen \_\_\_\_\_

Renal function at treatment onset (Creatinine Clearance mL/min)  
\_\_\_\_\_

### Information for medical staff:

Measuring INR is not suitable for assessment of the anticoagulant activity of Rivaroxaban Dexcel, and therefore should not be used for this purpose.

## Information regarding anticoagulants and instructions for the patient

- The anticoagulant Rivaroxaban Dexcel is a blood thinner, which protects you from the formation of dangerous blood clots.
- Rivaroxaban Dexcel must be taken exactly as prescribed by the doctor. To ensure optimal protection from blood clots, you should strictly comply with the administration schedule as recommended by the doctor and do not skip any tablet, unless instructed by the doctor.
- Do not stop taking Rivaroxaban Dexcel without consulting the doctor, as this may increase your risk of blood clots formation.

## Administration with food:

In order to ensure maximal treatment efficacy:

- **Rivaroxaban Dexcel 20 mg** – must be taken with food.
- **Rivaroxaban Dexcel 15 mg** – must be taken with food.
- **Rivaroxaban Dexcel 10 mg** – can be taken with or without food.
- **Rivaroxaban Dexcel 2.5 mg** – can be taken with or without food.

It is recommended to swallow the tablet with water. If it is hard for you to swallow the tablet whole, the tablet can be crushed and mixed with water or apple puree, immediately before administration. At dosages of 15/20 mg, eat immediately after taking the crushed medicine.

**If you forgot to take Rivaroxaban Dexcel at the designated time:**

**While taking Rivaroxaban Dexcel 10/15/20 mg:**

- At a dosage of 10/15/20 mg once daily – take a dose as soon as you remember, but never take a double dose or two doses on the same day!
  - At a dosage of 15 mg twice a day – [during the first three weeks of treatment for deep vein thrombosis (DVT) or pulmonary embolism (PE)], take a dose as soon as you remember. Do not take more than two 15 mg tablets in a single day. Two 15 mg tablets can be taken together to obtain a dosage of 30 mg on one day. On the following day, carry on taking one tablet of 15 mg twice a day.
- \* In any case of doubt, consult the doctor.

## **While taking Rivaroxaban Dexcel 2.5 mg:**

- Take the next dose at the usual time and consult a doctor. Do not take a double dose to make up for a forgotten dose.
- Tell the doctor about any other medicine that you are currently taking, have recently taken or intend to start taking, before starting treatment with Rivaroxaban Dexcel. This instruction also includes non-prescription medicines (including non-steroidal anti-inflammatory drugs, NSAIDs) and nutritional supplements.
- Inform your doctor that you are taking Rivaroxaban Dexcel before any invasive or surgical procedure is performed, including dental treatments.
- When taking an anticoagulant such as Rivaroxaban Dexcel, you should be aware of its possible side effects.
  - For a full list of side effects, carefully read the entire package insert.
  - Bleeding is the most common side effect.
  - If you know you are at risk of bleeding, do not start taking Rivaroxaban Dexcel before discussing this with your doctor.

## **Refer immediately to the doctor if you suffer from signs or symptoms that could indicate bleeding, such as:**

- Pain
- Paleness
- Unexplained swelling or discomfort
- Headache, dizziness, tiredness or exceptional weakness
- Breathlessness
- Chest pain or angina pectoris
- Abnormal subcutaneous hematomas, nosebleeds, bleeding from the gums, bleeding from cuts that does not stop for a long period of time
- Vaginal bleeding or abnormally increased menstrual bleeding
- Blood in the urine which may be pink or brown; red or black stools
- Coughing up blood or vomiting blood or material that looks like coffee grounds



**If you are at an increased risk of bleeding, you should discuss this/ consult with your doctor. The main risk factors for bleeding include, among others:**

- Moderate or severe kidney disease
- Liver impairment
- Medicines that affect blood clotting e.g., non-steroidal anti-inflammatory drugs, aspirin and other anticoagulants
- Uncontrolled and severe hypertension
- Bleeding disorders
- Disease of the stomach or bowel which may result in bleeding, e.g., inflammation of the bowel or stomach or inflammation of the esophagus due to, for example, gastroesophageal reflux disease
- Retinopathy
- Bronchiectasis or previous bleeding from the lung

## **Additional risk factors for bleeding for patients taking Rivaroxaban Dexcel 2.5 mg**

- Age 75 years and above
- Weight of 60 kg or less
- Coronary artery disease with severe symptomatic heart failure

## Reporting side effects and/or quality defects in the preparation

- **Side effects** can be reported to the Ministry of Health by clicking the link “דיווח על תופעות לוואי עקב טיפול תרופתי” found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)), directing to the online form for reporting side effects, or via the link: <https://sideeffects.health.gov.il>
- To report **side effects** and **quality defects in the preparation** contact Dexcel's customer service:  
Telephone: 04-6364016  
Email: [Customerservice@dexcel.com](mailto:Customerservice@dexcel.com)

For additional information, carefully read the entire package insert.  
Please refer to your doctor if you have any questions.

Approved in 01/2024