

PATIENT ALERT CARD
Dabitrان (Dabigatran etexilate)
75mg, 110mg, 150mg Capsules

Always keep this card with you!

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

➤ **Dabitrان (Dabigatran etexilate) Information for Patients**

- Dabitrان (Dabigatran etexilate) thins the blood, which prevents you from getting dangerous blood clots.
- Follow your doctor's instructions when taking Dabigatran. Never skip a dose or stop the intake of Dabitrان (Dabigatran etexilate) without talking to your doctor.
- Inform your doctor about all medicines you are currently taking.
- Inform your doctor about your intake of Dabitrان (Dabigatran etexilate) before any surgery/invasive procedure.
- Dabitrان (Dabigatran etexilate) can be taken with or without food. Swallow the capsule whole with a glass of water. Do not break, chew, or empty the pellets from the capsule.

➤ **When to seek medical advice**

- Taking Dabitrان (Dabigatran etexilate) may increase the risk of bleeding. Speak to your doctor immediately if you experience any of the following possible signs and symptoms of bleeding: swelling, discomfort, unusual pain or headache, dizziness, paleness, weakness, unusual bruising, nosebleeds, bleeding of gums, unusual long bleeding cuts, abnormal menstrual flow or vaginal bleeding, blood in your urine which may be pink or brown, red/black stools, coughing up blood, vomiting blood or coffee ground like material.
- If you fall or injure yourself, especially if you hit your head, urgently seek medical advice.
- Do not stop intake of Dabitrان (Dabigatran etexilate) without talking to your doctor, if you experience heartburn, nausea, vomiting, stomach discomfort, bloating or upper abdominal pain.

➤ **Dabitrان (Dabigatran etexilate) Information for Healthcare Professionals**

- Dabitrان (Dabigatran etexilate) is an oral anticoagulant (direct thrombin inhibitor).
- Dabitrان (Dabigatran etexilate) may need to be stopped in advance of surgical or other invasive procedures.
- In case of major bleeding events, Dabitrان (Dabigatran etexilate) must be stopped immediately.
- A specific reversal agent (Dabigatran) is Praxbind, idarucizumab is available (please refer to the Summary of Product Characteristics of Dabitrان (Dabigatran etexilate) for more information.).
- Dabitrان (Dabigatran etexilate) is mainly eliminated by the kidneys; adequate diuresis must be maintained. Dabitrان (Dabigatran etexilate) is dialyzable.

Please complete this section or ask your doctor to do it.

Patient information

Name of the patient:

Date of birth:

Indication for anticoagulation:

Dose of Dabigatran:

- Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
- Healthcare professionals are asked to report any suspected adverse reactions via the

National Pharmacovigilance & Drug Safety Centre at Saudi Food and Drug Authority (SFDA):

- Call Center: 19999
- E-mail: npc.drug@sFDA.gov.sa
- Website: <https://ade.sFDA.gov.sa/>

Marketing Authorization Holder Contact Information:

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