PATIENT ALERT CARD

Dabigatran etexilate 110 mg hard capsules
Dabigatran etexilate 150 mg hard capsules

- This card should be with you / the caregiver at all times
- Make sure to use the latest version

Version Dab-PAC-002 Revision date – November 2026

1

Dear Patient / Caregiver of a paediatric patient

Your / your child's doctor has initiated treatment with Dabigatran etexilate. In order to use Dabigatran etexilate safely, please consider the important information in the package leaflet.

As this patient alert card contains important information about your / your child's treatment, this card should be with you / your child at all times to inform healthcare professionals about your / your child's intake of Dabigatran etexilate.

2

Dabigatran etexilate:- Information for Patients / Caregivers of paediatric patients

About your / your child's treatment

- Dabigatran etexilate thins the blood. It is used to treat existing blood clots or to prevent the formation of dangerous blood clots.
- Follow your / your child's doctor's instructions when taking Dabigatran etexilate. Never skip a dose or stop the intake of Dabigatran etexilate without talking to your / your child's doctor.
- Inform your / your child's doctor about all medicines you / your child are / is currently taking.
- Inform your / your child's doctor about the intake of Dabigatran etexilate before any surgery / invasive procedure.

3

- Dabigatran etexilate capsules can be taken with or without food. The capsules should be swallowed whole with a glass of water. The capsule must not be broken or chewed and the pellets must not be emptied from the capsule.

When to seek medical advice

- Taking Dabigatran etexilate may increase the risk of bleeding. Speak to your / your child's doctor immediately if you / your child experience(s) signs and symptoms of bleeding such as: swelling, discomfort, unusual pain or headache, dizziness, paleness, weakness, unusual bruising, nosebleeds, bleeding gums, unusual long bleeding cuts, abnormal menstrual flow or vaginal bleeding, blood in the urine which may be pink or brown, red / black stools, coughing up blood, vomiting blood or coffee ground like material.

4

- In case of fall or injury, especially if the head is hit, urgently seek medical advice.
- Do not stop intake of Dabigatran etexilate without talking to your / your child's doctor, if you / your child experience(s) heartburn, nausea, vomiting, stomach discomfort, bloating or upper abdominal pain.

Dabigatran etexilate:- Information for Healthcare Professionals

- Dabigatran etexilate is an oral anticoagulant (direct thrombin inhibitor).
- Dabigatran etexilate may need to be stopped in advance of surgical or other invasive procedures.
- In case of major bleeding events, Dabigatran etexilate must be stopped immediately.

5

- A specific reversal agent (idarucizumab) is available for adult patients. The efficacy and safety of the specific reversal agent idarucizumab have not been established in paediatric patients.

For details and more advice to antagonise the anticoagulant effect of Dabigatran etexilate please refer to the Summary of Product Characteristics of Dabigatran etexilate and idarucizumab.

- Dabigatran etexilate is mainly eliminated by the kidneys; adequate diuresis must be maintained. Dabigatran etexilate is dialyzable.

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Please complete this section or ask your / your child's doctor to do it.

Patient Information

Name of patient

_____

Date of Birth

_____

Indication for anticoagulation

_____

Dose of Dabigatran etexilate hard capsules

_____

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