PATIENT ALERT CARD

ARX-Dabigatran capsules
dabigatran etexilate (as mesilate)

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

March 2024

Dear Patient,

Your doctor has initiated treatment with ARX-Dabigatran. In order to use ARX-Dabigatran safely, please consider the important information in this leaflet.

As this patient alert card contains important information about your treatment, this card should be with you at all times to inform healthcare professionals about your intake of ARX-Dabigatran.

ARX-Dabigatran Information for Patients

About your treatment

- ARX-Dabigatran thins the blood. It is used to treat existing blood clots or to prevent the formation of dangerous blood clots.
- Follow your doctor's instructions when taking ARX-Dabigatran. Never skip a dose or stop the intake of ARX-Dabigatran without talking to your doctor.
- Inform your doctor about all medicines you are currently taking.
- Inform your doctor about taking ARX-Dabigatran before any surgery / invasive procedure.
- ARX-Dabigatran capsules can be taken with or without food. The capsule 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 ARX-Dabigatran may increase the risk of bleeding.
- Speak to your doctor immediately if you experience signs and symptoms of bleeding such as: 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 the urine which may be pink or brown, red/black stools, coughing up blood, vomiting blood or coffee ground like material.
- In case of fall or injury, especially if the head is hit, urgently seek medical advice.
- Do not stop intake of ARX-Dabigatran without talking to your doctor, if you experience heartburn, nausea, vomiting, stomach discomfort, bloating or upper abdominal pain.

ARX-Dabigatran Information for Healthcare Professionals

- ARX-Dabigatran is an oral anticoagulant (direct thrombin inhibitor).
- ARX-Dabigatran may need to be stopped in advance of surgical or other invasive procedures.
- In case of major bleeding events, ARX-Dabigatran must be stopped immediately.
- A specific reversal agent (idarucizumab) is available for adult patients. The efficacy and safety of the specific reversal agent idarucizumab has not been established in paediatric patients.

For details and more advice to antagonise the anticoagulant effect of ARX-Dabigatran please refer to the Product Information document of ARX-Dabigatran and idarucizumab.

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

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

Patient Information

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Name of the patient

_____

Date of birth

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Indication for anticoagulation

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Dose of ARX-Dabigatran