

PATIENT ALERT CARD

319028-01



Pradaxa® capsules dabigatran etexilate

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

January 2021



Dear Patient / Caregiver of a paediatric patient,

Your / your child's doctor has initiated treatment with Pradaxa®. In order to use Pradaxa® 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 Pradaxa®.



1

Pradaxa® Information for Patients / Caregivers of paediatric patients

About your / your child's treatment

- Pradaxa® 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 Pradaxa®. Never skip a dose or stop the intake of Pradaxa® 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 Pradaxa® before any surgery / invasive procedure. 2
- Pradaxa® 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 Pradaxa® 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 of gums, unusual long bleeding cuts, abnormal menstrual 3

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 Pradaxa® without talking to your / your child's doctor, if you / your child experience(s) heartburn, nausea, vomiting, stomach discomfort, bloating or upper abdominal pain.

4

Pradaxa® Information for Healthcare Professionals

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

5

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

- Pradaxa® is mainly eliminated by the kidneys; adequate diuresis must be maintained. Pradaxa® is dialyzable.

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

Patient Information

6

Name of the patient

Date of birth

Indication for anticoagulation

Dose of Pradaxa®

7