

Treatment of blood clots and prevention of blood clots from reoccurring in children

Common (may affect up to 1 in 10 people):

- A fall in the number of red cells in the blood
- A fall in the number of platelets in the blood
- Skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- Sudden change of the skin which affects its colour and appearance
- Haematoma formation
- Nosebleed
- Reflux of gastric juice into the gullet
- Vomiting
- Feeling sick
- Frequent loose or liquid bowel movements
- Indigestion
- Hair loss
- Liver enzymes increased

Uncommon (may affect up to 1 in 100 people):

- Decrease in the number of white blood cells (which help to fight infections)
- Bleeding may happen into the stomach or bowel, from the brain, from the rectum, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- A decrease in the proportion of blood cells
- Itching
- Coughing of blood or blood stained sputum
- Belly ache or stomach ache
- Inflammation of the gullet and stomach
- Allergic reaction
- Difficulty in swallowing
- Yellowing of the skin or whites of the eyes, caused by liver or blood problems

Not known (frequency cannot be estimated from the available data):

- Lack of white blood cells (which help to fight infections)
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Serious allergic reaction which causes swelling of the face or throat
- Difficulty in breathing or wheezing
- Bleeding
- Bleeding may happen into a joint or from an injury, from a surgical incision, or from the site of entry of an injection or from the site of entry of a catheter into a vein
- Bleeding may happen from piles
- Ulcer in the stomach or bowel (incl. ulcer in the gullet)
- Unusual laboratory test results on liver function

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Pradaxa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, blister or bottle after "EXP". The expiry date refers to the last day of that month.

Blister: Store in the original package in order to protect from moisture.

Bottle: Once opened, the medicine must be used within 4 months. Keep the bottle tightly closed. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pradaxa contains

- The active substance is dabigatran. Each hard capsule contains 75 mg dabigatran etexilate (as mesilate).
- The other ingredients are tartaric acid, acacia, hypromellose, dimeticone 350, talc and hydroxypropylcellulose.
- The capsule shell contains carrageenan, potassium chloride, titanium dioxide and hypromellose.
- The black printing ink contains shellac, iron oxide black and potassium hydroxide.

What Pradaxa looks like and contents of the pack

Pradaxa 75 mg are hard capsules (approx. 18 × 6 mm) with an opaque, white cap and an opaque, white body. The Boehringer Ingelheim logo is printed on the cap and "R75" on the body of the hard capsule.

This medicine is available in packs containing 10 × 1, 30 × 1 or 60 × 1 hard capsules in aluminium perforated unit dose blisters. Furthermore, Pradaxa is available in packs containing 60 × 1 hard capsules in aluminium perforated unit dose white blisters.

This medicine is also available in polypropylene (plastic) bottles with 60 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Boehringer Ingelheim Ltd.
Tel: +44 1344 424 600

This leaflet was last revised in 02/2024.

PATIENT ALERT CARD P053547-003

Pradaxa® capsules
dabigatran etexilate

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

February 2024



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®.



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

Perigord No: 809393 P1

File information		Mandatory in	
		TD	Printfile
Issue date of TD:	10.01.2024	Yes	Yes
PPM SKU:	P053547	No	Yes
PPM SKU version:	003	No	Yes
Issue date of artwork:	15.05.2024	No	Yes
Print colors:	PAN BLACK PAN 200 PAN 293	No	Yes
Mat. No. Pack. Site:	P053547-003	No	Yes
Min. font size:	8.55 pt		
Legend case version:	V5.0 01/JAN/2021 (please do not change or remove it)		

Technical colours - not for printing

BI-Diecut-Legendcase	Free area	Gluepoints
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Additional Requirements of Packaging site

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Only for BI-internal use, Template according to Drawing no.: SP-14-0077-001-B_Index_e	

In-process control code specification

Technical information
Control Code Type:
Laetus Code

MASS D: 0,5 mm
MASS E: 1,5 mm
MASS G: 1 mm

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.

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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.

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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

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Name of the patient

Date of birth

Indication for anticoagulation

Dose of Pradaxa®

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