

PATIENT ALERT CARD

Pradaxa® Dabigatran etexilate

Boehringer Ingelheim Middle East, Turkey, and Africa Regional Operating Unit
P.O. Box 505123, Dubai Healthcare City, Dubai, United Arab Emirates
Website: www.boehringer-ingelheim.com/mena/
Tel: +971 4 4230400 Fax: +971 4 4233637

• Keep this card with you at all times

Any adverse reactions should be reported in accordance with the Saudi Vigilance spontaneous reporting system to:
The National Pharmacovigilance and Drug Safety Centre NPC
Email: npc.drug@sfdca.gov.sa
Fax: +966112057662
Phone +966-11-2038222 Ext : 2317 -2356- 2353-2354- 2334-2340
Toll free phone: 8002490000

In addition, suspected adverse reactions related Boehringer Ingelheim products may be reported to Boehringer Ingelheim Pharmacovigilance department:
Email: PV_Local_Saudi_Arabia@boehringer-ingelheim.com
Phone: +966-11-207 8275



Dear Patient,

Your doctor has initiated treatment with Pradaxa® (dabigatran etexilate). In order to use Pradaxa® safely, please consider the important information inside.

As this patient alert card contains important information about your treatment, please carry this card with you at all times to inform healthcare professionals about your intake of Pradaxa®.



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Pradaxa®: Information for Patients

Follow your doctor's instructions when taking Pradaxa®.

- Pradaxa® prevents clots by making your blood less "sticky". However, this may increase the risk of bleeding.
- In case of a bleeding event which does not stop spontaneously, immediately inform your doctor.
- If you fall or injure yourself during treatment, especially if you hit your head, please seek urgent medical attention. You may need to be checked by a doctor, as you may be at increased risk of bleeding.
- As Pradaxa® acts on the blood clotting system, most side effects are related to signs of bruising or bleeding. Signs and symptoms of bleeding events might be haematoma of the skin, tar stools, blood in urine, nose bleed, etc.
- If surgical or invasive procedures need to be performed, inform the treating physician about your intake of Pradaxa®.
- Do not stop the intake of Pradaxa® without talking to your doctor, as you are at risk of suffering from a stroke or other complications due to blood clot formation.
- In the case of bleeding, please contact your doctor before stopping the intake of Pradaxa®.
- Take Pradaxa® regularly as instructed and do not miss a dose.
- Inform your doctor about all medicines you are currently taking.

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- Pradaxa® can be taken with or without food. The capsule should be swallowed whole with a glass of water, to ensure delivery to the stomach. Do not break, chew, or empty the pellets from the capsule since this may increase the risk of bleeding.

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Pradaxa® Information for Healthcare Professionals

- Pradaxa® is an oral anticoagulant acting by direct thrombin inhibition and is eliminated predominantly via the kidney.
- In case of surgical or other invasive procedure, Pradaxa® needs to be stopped in advance (for more details see Summary of Product Characteristics).
- In case of major bleeding events, Pradaxa® must be stopped immediately.

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- Since Pradaxa® is eliminated predominantly by the kidneys, adequate diuresis must be maintained. Pradaxa® is dialyzable, but there is limited clinical experience (for details and more advice to antagonize the anticoagulant effect of Pradaxa®, see Summary of Product Characteristics).

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

Patient Information

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(Name of the patient)

(Date of birth)

(Indication for anticoagulation)

(Dosage of Pradaxa®)

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