Important guidelines for PRADAXA® patient

About your treatment

- PRADAXA® prevents formation of dangerous blood clots.
- Follow your doctor's instructions when taking PRADAXA®. Never skip a dose or stop the intake of PRADAXA® without talking to your doctor.
- Consult your doctor prior to taking nonprescription medications and nutritional supplements.
- Inform your doctor about all additional medicines you are currently taking.
- Inform your doctor about your intake of PRADAXA® before any surgery or invasive procedure (including dentist).
- PRADAXA® can be taken with or without food. Swallow the capsule whole with a full glass of water. Do not break, chew, or empty the pellets from the capsule.
- If you are receiving PRADAXA® for prevention of VTE (venous thromboembolism) following orthopedic surgery, and you forgot to take the medicine, take the next dose of PRADAXA® on the next day at the usual time.
- If you are receiving PRADAXA® for prevention of stroke or as a treatment for deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of their recurrence, and you forgot to take the medicine, take the dose as soon as you remember, but only if there are at least 6 hours left until the next dose.
- If you are receiving nonsteroidal anti-inflammatory drugs (e.g. Nurofen or Advil), consult your attending doctor since they may significantly increase your risk of bleeding.
- Pay attention to the following risk factors, which may increase the risk of bleeding: age above 75 years, previous significant bleeding, renal disorder, hepatic disorder, esophageal or gastric inflammation, taking medicines affecting blood coagulation- such as aspirin and other anticoagulants.
- For complete information about the medicine, see the Patient Leaflet enclosed with the medicine package.

Consult your doctor immediately in the following situations:

- Taking PRADAXA® may increase the risk of bleeding. Speak to your doctor immediately if you experience any of the following possible signs and symptoms of bleeding, which include: 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 your urine which may be pink or brown, red/black stools, coughing up blood, vomiting blood or coffee ground like material.
- If you fall or injure yourself during the treatment, especially if you hit your head, urgently seek medical advice.
- Do not stop intake of PRADAXA® without talking to your doctor.

Ask your attending doctor to complete the following data:

Name of the patient:

Date of birth:

Blood type:

Aim of the treatment (check the appropriate box):

- ☐ Prevention of stroke
- ☐ Prevention of VTE following orthopedic surgery
- ☐ Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) and prevention of their recurrence

Dosage and times of intake:

(e.g. 150 mg twice a day, 8 a.m. and 8 p.m.)

Renal function at the beginning of treatment CrCl ml/min

PRADAXA® is not allowed for patients with CrCl values below 30 ml/min. Dose adjustment is required in certain medical conditions (for complete details, see Prescribing Information Leaflet).

Date of treatment initiation:

Name of attending doctor:

Tel. no. of attending doctor:

In case of receiving medical treatment including emergency treatment, notify the medical staff of taking PRADAXA®.

For situations of life-threatening or uncontrolled bleeding, when rapid reversal of the anticoagulation of PRADAXA® is required, the specific reversal agent PRAXBIND® is available.

Emergency contact

Name

Mobile phone no.

Dear patient,

Your doctor has initiated treatment with PRADAXA® for you. To ensure effective and safe treatment, please keep this card and comply with the provided instructions.

As this patient alert card contains important information about your treatment, please carry this card with you at all times, and present it to healthcare professionals treating you in order to inform them about your intake of PRADAXA®.

PRADAXA® Information for Healthcare Professionals

- PRADAXA® is a direct thrombin inhibitor oral anticoagulant.
- 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 (PRAXBIND®) is available (please refer to the Prescribing Information of PRADAXA® and PRAXBIND®).
- PRADAXA® is mainly eliminated by the kidneys; adequate diuresis must be maintained. PRADAXA® is dialyzable.

Reporting side effects

Side effects can be reported to the Ministry of Health (MoH) by the portal for side effects reporting in the MoH home page www.health.gov.il

or by the link:
https://sideeffects.health.gov.il/

You can also report side effects to Boehringer Ingelheim Israel:

Boehringer Ingelheim Israel Ltd.
89 Medinat Ha-Yehudim St.
P.O. Box 4124, Hertzliya-Pituah, Israel 4676672
Phone: 09-9730500, Fax: 09-9730549

Safety information card for a patient treated with PRADAXA® (Dabigatran Etexilate)

Keep this card with you at all times

Make sure to use the latest version

The format and content of this information card has been updated and approved by the Ministry of Health in June 2019.

Boehringer Ingelheim

Pradaxa® dabigatran etexilate