

Important guidelines for Dabigatran Teva®

About your treatment

- Dabigatran Teva® prevents formation of dangerous blood clots.
- Follow your doctor's instructions when taking Dabigatran Teva®. Never skip a dose or stop the intake of Dabigatran Teva® 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 Dabigatran Teva® before any surgery or invasive procedure (including dentist).
- Dabigatran Teva® 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 Dabigatran Teva® for prevention of VTE (venous thromboembolism) following orthopedic surgery, and you forgot to take the medicine, take the next dose of Dabigatran Teva® on the next day at the usual time.
- If you are receiving Dabigatran Teva® 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 Dabigatran Teva® 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 Dabigatran Teva® 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

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

Emergency contact

Name

Mobile phone no.

Dear patient,

Your doctor has initiated treatment with Dabigatran Teva[®] 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 Dabigatran Teva[®].



Dabigatran Teva[®] Information for Healthcare Professionals

- Dabigatran Teva[®] is a direct thrombin inhibitor oral anticoagulant.
- Dabigatran Teva[®] may need to be stopped in advance of surgical or other invasive procedures.
- In case of major bleeding events, Dabigatran Teva[®] must be stopped immediately.
- A specific reversal agent (PRAXBIND[®]) is available (please refer to the Prescribing Information of Dabigatran Teva[®] and PRAXBIND[®]).
- Dabigatran Teva[®] is mainly eliminated by the kidneys; adequate diuresis must be maintained. Dabigatran Teva[®] is dialyzable.

Reporting side effects

Side effects can be reported to the Ministry of Health using the online form. for side effect reporting that is found in the Ministry of Health homepage:

www.health.gov.il

or via the link:

<https://sideeffects.health.gov.il>

or through the registration holder Teva Israel Ltd via:

safety.israel@teva.co.il

More information

Teva Israel Ltd. P.O.B 3190
124 Dvora HaNevi'a St. Tel Aviv, Israel
Phone: 1-800-805-005



**Safety information
card for a patient
treated with
Dabigatran Teva[®]**

**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 September 2022.