

## Concomitant Medications

Medication	Dose

### Cases which require seeking immediate medical attention:

Bleeding, which may be life threatening. An allergic reaction, including rash, edema, swelling of the face, lips, mouth, tongue and/or throat, and breathing difficulty (rare).

### Side effects:

**Side effects may occur when taking anticoagulants. You should be aware of them and seek medical treatment if necessary. For a full list of side effects, see the consumer leaflet. The most common side effect is bleeding.**

## Expressions of hemorrhaging may include, among others

- Gastro-intestinal bleeding, which may be expressed by blood in stools or black/dark stools, pain (such as abdominal pain) and swelling
- Blood in urine (red or pink urine), blood in urine discovered in a urine test
- Bleeding eyes, nose or gums
- Bloody cough and bloody vomit (vomiting of blood or a granular coffee-like substance)
- Secretion of blood or fluids from cuts and wounds, cuts that bleed for a long time
- Unusual bleeding or bleeding that fails to stop spontaneously
- Headache, dizziness, anemia expressed in fatigue and pallor, nausea

## Risk factors of increased bleeding may be:

A liver disease which causes a coagulation disorder and risk of bleeding.

An injury or medical condition with an increased risk of bleeding, such as an active or recent stomach or intestinal ulcer, malignant tumor with increased risk of bleeding, recent brain or spinal injury, recent

intracranial bleeding, esophageal varices or suspected varices, arterio-venous malformation, aneurysm or significant vascular anomaly of the brain or spinal cord. If you have recently undergone brain, spinal or eye surgery.

If you are taking other anticoagulants, apart from situations of transition from or to **Apixaban Teva** therapy, or if you have an intravenous or arterial catheter that requires administration of heparin through it in order to keep it open.

If you are scheduled to undergo surgery or a medical procedure that may cause bleeding, including dental care, consult your physician. As a result, you may be requested by your physician to discontinue the treatment for a short period. If you are certain the medical procedure is likely to cause bleeding, consult your physician.

## REPORTING OF SUSPECTED ADVERSE REACTIONS

For further information, see the consumer leaflet approved by the Ministry of Health

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](http://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](mailto: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

This card was approved in accordance with the instructions of the Ministry of Health in February 2023

## The bearer of this card is treated with Apixaban Teva

Patient's Name:

Date of Birth:

Address:

Treatment (dose, times taken, with or without food):

Indication / objective of treatment:

Date of treatment commencement:

Attending physician's name/telephone:

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Information of patient's relative in case of emergencies (name, relationship, telephone no.):

Blood type (with physician's signature):

Weight:

Creatinine clearance rate at treatment commencement:

This Patient Safety Information Card should be carried with you at all times.

Make sure to use the latest version.

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## Dose adjustment in the case of renal impairment:

**Apixaban Teva** is not recommended in patients with creatinine clearance < 15 mL/min, or in patients undergoing dialysis.

## For non-valvular atrial fibrillation patients:

The dose must be adjusted in the following cases:

1. Creatinine clearance of **15-29** ml/min
2. If **at least two** of the following **three** criteria are met:
  - A. Age 80 or over
  - B. Weight of 60 kg or less.
  - C. Serum creatinine concentration of 1.5 mg/dl or more

Refer to your treating physician if you are not certain whether these conditions apply.

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## Objective of treatment



2.5/5 mg

For the prevention of stroke and embolism in non-valvular atrial fibrillation (NVAf)



2.5/5 mg

For the treatment of deep vein thrombosis (DVT) and PE (pulmonary embolism)



2.5 mg

For the prevention of deep vein thrombosis (DVT) and PE (pulmonary embolism)



2.5 mg

For the prevention of thrombotic events:  
- Following elective hip replacement surgery  
- Following elective knee replacement surgery



For full information of the indications as approved by the Ministry of Health, see the consumer leaflet.

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## Dose and Administration Times

The dose and method of treatment will be determined by a physician only. The medication is usually taken twice daily. Try to take the medication at fixed times daily in order to obtain optimal effect of the treatment.

## Route of Administration

- Swallow the tablet with a drink of water. **Apixaban Teva** can be taken with or without food
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take **Apixaban Teva**
- The tablet may be crushed and mixed with water, or 5% dextrose in water, apple juice or apple puree, immediately before you take it. For full crushing instructions, please see the patient leaflet
- If necessary, your doctor may also give you the crushed **Apixaban Teva** tablet mixed in 60 mL of water or 5% dextrose in water through a nasogastric tube
- Do not exceed the recommended dose

**In case of an overdose or if a child swallows the medication by mistake**, see a physician or go to the hospital emergency room immediately and bring the medication package with you. Overdosing may cause bleeding. In case of bleeding, you may require a blood transfusion or surgery.

If you forget to take this medication at the fixed time,

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take a dose immediately and the next dose at the usual time. Then continue according to the routine recommended dosage. If you are not sure what to do or have missed more than one dose, consult a physician, pharmacist or nurse.

## Recommended follow up at each visit

- Consistency and compliance with the treatment instructions
- Monitoring of bleeding events and other side effects. It is recommended to have blood tests according to the physician's orders. Even if your health improves, you should not discontinue the medication without consulting a physician or pharmacist.

**If you stop taking the medication**, you may suffer from development of blood clots.

**If you are taking or have recently taken other medication, including OTC medication and dietary supplements, tell your physician, pharmacist or nurse.**

**The physician, pharmacist or nurse should be informed especially if you are taking rifampin (antibiotic), phenytoin, phenobarbital, carbamazepine (epilepsy treatment), and st. john's wort: They reduce the blood Apixaban Teva level and may reduce its efficacy**

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