

**Apixaban Taro 2.5 mg / Apixaban Taro 5 mg
Patient Safety Information Card**

(apixaban 2.5 mg, apixaban 5 mg)

The bearer of this card being treated with Apixaban Taro

Patient's name:
Date of birth:
Address:
Treatment (dose, times taken, with or without food):
Indication / objective of treatment:
Treatment start date:
Doctor's name / telephone:
Emergency contact information (name, relationship to patient, telephone no.):
Blood type (with the doctor's signature):
Weight:
Creatinine clearance rate at start of treatment:

Please keep this Patient Safety Information Card within reach at all times.
Please make sure that you are using the most current version of the card.
This card was approved in June 2024 according to the guidelines of the Ministry of Health.

Refer to the patient information leaflet for more information.

Dose adjustment in case of poor kidney function:

Apixaban Taro is not recommended if you have kidney failure (creatinine clearance < 15 ml/min) or if you are undergoing dialysis.

For non-valvular atrial fibrillation patients (NVAf), 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 higher.

Contact your doctor if you are not certain whether these conditions apply to you.

Objective of treatment

Apixaban Taro 2.5 mg / Apixaban Taro 5 mg For the prevention of stroke and systemic embolism in non-valvular atrial fibrillation (NVAF) patients
Apixaban Taro 2.5 mg / Apixaban Taro 5 mg For the treatment of blood clots in the leg veins (deep vein thrombosis – DVT) and in the blood vessels of the lungs (pulmonary embolism – PE)
Apixaban Taro 2.5 mg For the prevention of recurrent blood clots in the leg veins (deep vein thrombosis – DVT) and in the blood vessels of the lungs (pulmonary embolism – PE)
Apixaban Taro 2.5 mg For the prevention of thrombotic events: <ul style="list-style-type: none">- Following elective hip replacement surgery- Following elective knee replacement surgery

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

Dose and Administration Times

Only your doctor will determine your dose and how you should take this medicine. The medicine is taken twice daily. Try to take the medicine at set times daily in order to obtain optimal effect of the treatment.

How to take this medicine

- Swallow the medicine with water. The medicine 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 Taro.
- The tablet may be crushed and mixed with water, 5% dextrose in water, apple juice or apple sauce immediately before you take it. For detailed crushing instructions, please see the patient information leaflet in the package.
- If necessary, your doctor may give you the Apixaban Taro through a nasogastric tube.
- Do not exceed the recommended dose.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. An overdose may cause bleeding. In case of bleeding, you may require a blood transfusion or surgery.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, and take the next dose 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 your doctor, pharmacist or nurse.

Recommended follow up at each visit:

- Adherence and compliance with the treatment instructions,
- Monitoring of bleeding events and other side effects.

It is recommended to have blood tests according to the doctor's orders.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

If you stop taking this medicine, you may develop blood clots.

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor, pharmacist or nurse.

The physician, pharmacist or nurse should be informed especially if you are taking rifampin (antibiotic), phenytoin, phenobarbital, carbamazepine (epilepsy treatment), St John's wort: medicines that reduce the concentration of Apixaban Taro in the blood and may therefore reduce its efficacy.

Medicines administered at the same time

Medicine	Dosage

Cases that require 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, 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 patient information leaflet. The most common side effect is bleeding.

Expressions of bleeding may include, among others:

- Gastrointestinal bleeding, which may be expressed by blood in stools (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 Taro 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 doctor. As a result, you may be requested by your doctor to discontinue the treatment for a short period. If you are uncertain that the medical procedure may cause bleeding, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health using the portal for reporting side effects, which can be found on the homepage of the Ministry of Health website:

www.health.gov.il or by using this link: <https://sideeffects.health.gov.il>.

Side effects may also be reported to Taro by e-mail: drug.safety@taro.com

For more information about the medicine and for up-to-date cards in Hebrew, Arabic and English, scan the following QR code:



https://www.gov.il/he/Departments/DynamicCollectors/patient-safety-information?skip=0&safety_information_lang=3

To receive a hard copy of the card in Arabic/English, contact Taro:

Phone: 04-8475700 E-mail: info@taro.com



Taro International Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Version V.1