

The person carrying this card is being treated with –

## **APIX**

Patient name:
Date of birth:
Address:
Treatment (dosage, administration times, with or without food):
Indication/Treatment objective:
Treatment start date:
Treating doctor – name/telephone:
Details of patient's relative for emergency situations (name, relation, telephone):
Blood type (with doctor's signature):
Weight:
Creatinine clearance rate at treatment initiation:

Please keep this safety information card available at all times.  
Please be sure that you are using the most updated version of the card.  
This card was approved in accordance with the Ministry of Health guidelines in August 2025.

Read the patient leaflet for more information.

### **Adjustment of the dosage in case of renal impairment**

**Apix** is not recommended if you are suffering from kidney failure (creatinine clearance below 15 ml/min) or if you are being treated with dialysis.

For patients with non-valvular atrial fibrillation (NVAf), the dosage should be adjusted in the following cases:

1. creatinine clearance 15-29 ml/min. 2. In cases in which **at least two of three criteria** are met: a. age 80 or above. b. weight 60 kg or less. c. serum creatinine concentration 1.5 mg/dl or above.

Refer to the attending doctor if you are not sure if these conditions apply to you.

### **Treatment objective**

2.5/5 mg

For prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf).

### 2.5/5 mg

For treatment of blood clots in the leg veins (deep vein thrombosis – DVT) and in the blood vessels of the lungs (pulmonary embolism – PE).

### 2.5 mg

For prevention of recurrence of blood clots in the leg veins (deep vein thrombosis – DVT) and in the blood vessels of the lungs (pulmonary embolism – PE).

### 2.5 mg

For prevention of venous thrombotic events:

- following elective hip replacement surgery.
- following elective knee replacement surgery.

See the patient leaflet for full details of the indications approved by the Ministry of Health.

### **Dosage and administration times**

The dosage and treatment regimen will be determined by the doctor only. The medicine is taken twice a day. Try to take the medicine at regular times every day, in order to obtain the optimal effect of the treatment.

### **Route of administration**

- 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 possible ways to take **Apix**.
- The tablet may be crushed and mixed with water, 5% dextrose in water, apple juice or apple puree immediately before taking it. For detailed crushing guidelines, please see the patient leaflet provided with the package.
- If needed, your doctor can give you **Apix** via a nasogastric tube.
- Do not exceed the recommended dose.

**If you took an overdose, or if a child has accidentally swallowed the medicine**, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Overdose may lead to bleeding. In case of bleeding, you may need a blood transfusion or surgery.

**If you forget to take the medicine** at the scheduled time, take the dose as soon as possible on the same day and continue taking the medicine twice daily (and no more). Do not double the dose to make up for the missed dose. If you are uncertain as to what to do or if you missed more than one dose, consult the doctor, pharmacist or nurse.

### **Follow-up recommended at each visit:**

- Adherence and compliance with treatment instructions.
- Follow-up of bleeding events and other side effects.

It is recommended to perform blood tests per the doctor's instructions.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist. **If you stop taking the medicine**, you may develop blood clots.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor, pharmacist or nurse.**

**It is particularly important to inform the doctor, pharmacist or nurse if you are taking: rifampin (antibiotic), phenytoin, phenobarbital and carbamazepine (to treat epilepsy), Hypericum (St. John's wort): these medicines lower the concentration of Apix in the blood and may thereby reduce its efficacy.**

**Concomitant medicines**

Name of the medicine	Dosage

**Situations that require immediate referral to a doctor:**

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

**Side effects**

**Side effects may occur when taking anticoagulants; you should be aware of them and refer for medical treatment if necessary. Read the patient leaflet for the full list of side effects. The most common side effect is bleeding.**

**Manifestations of bleeding may include, among others:**

- Gastrointestinal bleeding, which may manifest by blood in the stools (black/dark stools), pains (e.g., abdominal pains) and swelling.
- Blood in the urine (red or pink urine), blood in the urine detected in a urine test.
- Bleeding from the eyes, nose or gums.
- Bloody cough and vomit (vomiting blood or a substance like coffee grounds).
- Discharge of blood or fluids from cuts and wounds, cuts bleeding for long periods of time.
- Abnormal bleeding or bleeding that does not stop spontaneously.
- Headache, dizziness, anemia manifesting by tiredness, pallor, nausea.

**Risk factors for increased bleeding may be:**

A liver disease that causes a coagulation disturbance and risk of bleeding.

An injury or a medical condition with increased risk of bleeding, such as: active or recent gastric or intestinal ulcer, a malignant tumor with increased risk of

bleeding, recent injury to the brain or spinal cord, recent intracranial bleeding, existing or suspicion of esophageal varices, arteriovenous malformation, aneurysm or significant impairment of blood vessels in the brain or spinal cord. If you recently underwent brain surgery, spinal cord surgery or eye surgery.

If you are taking other anticoagulants, with the exception of cases of switching treatment or switching to treatment with **Apix** or if an intravenous or intra-arterial catheter is inserted to keep it open for administration of heparin.

If you are due to undergo surgery or a medical procedure that may cause bleeding, including dental treatment, consult the doctor. You may consequently be told by the doctor to stop treatment with the medicine for a short period. If you are unsure if a medical procedure may cause bleeding, consult the doctor.

### **Reporting side effects**

Side effects may be reported to the Ministry of Health through the Side Effects Reporting portal found on the Ministry of Health homepage: [www.health.gov.il](http://www.health.gov.il) or through the following link: <https://sideeffects.health.gov.il>

Side effects can also be reported to Unipharm by email:

[Safety\\_first@unipharm.co.il](mailto:Safety_first@unipharm.co.il)



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