

APICOG-2.5, APICOG-5 FILM COATED TABLETS

Apixaban (2.5 mg, 5 mg)

What is in this leaflet

1. What APICOG is used for
2. How APICOG work
3. Before you use APICOG
4. How to take APICOG
5. While you are using APICOG
6. Side Effects
7. Storage and Disposal of APICOG
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What APICOG is used for

APICOG contains apixaban as the active ingredient.

Apixaban is used to:

- prevent blood clots in veins (venous thromboembolic events (VTE)) after a hip or knee replacement surgery.
- prevent stroke and blood clots in adult patients with a condition called non-valvular atrial fibrillation, which is a type of irregular heart rhythm with one or more risk factors, such as:

- prior stroke or transient ischaemic attack (TIA) (mini stroke);
- age ≥ 75 years
- high blood pressure (hypertension)
- high blood sugar levels (diabetes mellitus)
- symptomatic heart failure (NYHA Class $\geq$ II).

- treat blood clots occurring in deep veins (Deep Vein Thrombosis [DVT]) and clots in your lungs (Pulmonary Embolism [PE]) and also to prevent these from recurring.

How APICOG work

APICOG works by preventing blood clot formation by inhibiting Factor Xa, which is an important component of blood clotting.

Before you use APICOG

-When you must not take it

Do not take APICOG if you:

- are allergic to apixaban and any of its ingredients

- have an injury to a body organ or any internal bleeding

- have liver disease associated with a bleeding disorder called coagulopathy and an increased risk of bleeding

- have any condition or injury to a body organ that could lead to significant bleeding (such as ulcers in stomach; cancerous growth; recent brain or spinal injury; recent brain, spinal or eye surgery; bleeding in the brain; abnormal, enlarged veins in the tube that connects the throat and stomach (esophagus); an abnormal connection between arteries and veins, a bulging, dilation or ballooning in the wall of a blood vessel; abnormalities within brain or spine)

- are taking medicines to prevent blood clotting like heparins, heparin derivatives, warfarin, rivaroxaban and dabigatran

- have severe kidney disease or kidney failure or if you are undergoing treatment (dialysis).

Pregnancy and lactation

Do not take APICOG if you are pregnant, trying to get pregnant or think you may be pregnant.

It is not known if APICOG passes into human breast milk. Ask your doctor, pharmacist or nurse for advice before taking this medicine while breastfeeding.

They will advise you to either stop breast-feeding or to stop/not start taking APICOG.

Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to take it

Tell your doctor or pharmacist if you have/are:

- any condition with increased risk of bleeding that affect your ability to form clots

- atrial fibrillation along with other conditions that requires mono or dual antiplatelet therapy

- undergoing procedures such as spinal/epidural anaesthesia or puncture and treated with

antithrombotic agents to prevent clot

- a prosthetic heart valve

- surgery or a procedure which may cause bleeding

- cancer

- any kidney or liver disease

- are elderly and have low body weight less than 60 kg

- having hip fracture surgery

- to undergo any clotting tests

- know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots),

- hereditary problems of galactose intolerance

- taking acetylsalicylic acid (ASA) as it increases the risk for bleeding in patients treated with APICOG.

-Taking other medicines

Tell your doctor if you are already taking or using any of the following as they may interact with your medicine:

- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole and posaconazole, fluconazole

- antibacterial medicine such as rifampicin

- anti-viral medicines for HIV/AIDS e.g. ritonavir

- medicines to treat epilepsy such as phenytoin, carbamazepine and phenobarbital

- St. John's wort (a herbal supplement used for depression)

- medicines used to treat pain and inflammation including non-steroidal anti-inflammatory drugs (NSAIDs) such as naproxen or aspirin

- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin

- other medicines used to prevent blood clots such as clopidogrel, prasugrel, dipyridamole, dextran and sulfapyrazone

- medicines for high blood pressure or heart problems (e.g., diltiazem, amiodarone, verapamil, quinidine, atenolol, digoxin)

APICOG-2.5, APICOG-5 FILM COATED TABLETS

Apixaban (2.5 mg, 5 mg)

- other antibiotics like clarithromycin
- other medicines such as famotidine and activated charcoal

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

How to take APICOG

-How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

To prevent blood clots from forming after hip or knee replacement operations:

The recommended dose is one tablet of APICOG-2.5 twice a day with first dose taken 12-24 hours after surgery.

To prevent a blood clot from forming in the heart in patients with an irregular heart beat:

The recommended dose is one 5 mg tablet twice a day.

The recommended dose reduction is 2.5 mg tablet twice daily if the patient experiences at least two of the three conditions listed below:

- your blood test results suggest poor kidney function (value of serum creatinine is 1.5 mg/dL (133 micromole/L) or greater)
- you are 80 years old or older
- your weight is 60 kg or lower.

To treat blood clots occurring in deep veins (Deep Vein Thrombosis [DVT]) lungs (Pulmonary Embolism [PE]):

The recommended dose is two 5 mg tablets twice a day for the first 7 days followed by 5 mg twice daily.

Short duration of treatment (at least 3 months) should be based on transient risk factors (e.g., recent surgery, trauma, immobilisation).

To prevent recurrent blood clots occurring in deep veins (Deep Vein Thrombosis [DVT]) lungs (Pulmonary Embolism [PE]):

The recommended dose is one 2.5 mg tablet orally twice daily following completion of 6 months of treatment for DVT or PE with 5 mg twice daily or with another anticoagulant.

Changing from treatment with anticoagulant containing vitamin K antagonist (e.g., warfarin) to APICOG:

Stop taking the medicine containing a vitamin K antagonist. You need to do blood-measurements and your doctor will instruct you when to start APICOG.

Changing from APICOG to anticoagulant treatment containing vitamin K antagonist (e.g., warfarin):

If you have to start taking the medicine containing a vitamin K antagonist, continue to take APICOG for at least 2 days after your first dose of the medicine containing a vitamin K antagonist. Your doctor needs to do blood measurements and instruct you when to stop taking APICOG.

Patients undergoing cardioversion:

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take APICOG at the times your doctor tells you to do. You have to take one 5 mg tablet twice daily for at least 2.5 days (5 single doses) before cardioversion.

If you require cardioversion before completing 5 doses, 10 mg loading dose should be given first, followed by 5 mg twice daily. Your doctor may reduce the dose if you meet the criteria for dose reduction.

Your doctor will take confirmation that you have taken APICOG as prescribed before undergoing cardioversion.

You can continue using APICOG while undergoing a procedure called catheter ablation, in which

the doctor advances a flexible thin tube (catheter) through the blood vessels of your heart to stop abnormal electrical signals in the heart tissue.

Patients who have irregular and often rapid heart rate (atrial fibrillation)/sudden reduced blood flow to heart (acute coronary syndrome) or undergoing a nonsurgical procedure that improves blood flow to your heart percutaneous coronary intervention should consult with their doctor before taking APICOG.

- When to take it

Swallow the tablet(s) whole with a glass of water, with or without food. If you are unable to swallow whole tablets, APICOG tablets may be crushed and suspended in water, or 5% dextrose in water or apple juice or mixed with apple puree and immediately administered orally.

Alternatively, crushed and suspended in 60 mL of water, or 5% dextrose in water and immediately delivered through a nasogastric tube.

Take your medicine as directed by your doctor.

Take your medicine at about the same time each day.

-How long to take it

Take APICOG daily as prescribed by your doctor.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, you may be at an increased risk of developing a blood clot.

If you have had a major hip operation you will usually take the tablets for 32 to 38 days.

If you have had a major knee operation you will usually take the tablets for 10 to 14 days.

If you have blood clots (VTE):

To treat blood clots, you will usually take the tablets for up to 6 months. If necessary, you may need to continue taking the tablets,

APICOG-2.5, APICOG-5 FILM COATED TABLETS

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usually at a lower dose, to prevent further blood clots.

If you have atrial fibrillation:

Continue taking your medicine for as long as your doctor tells you.

-If you forget to take it

If you forget to take APICOG, take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

-If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this APICOG. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include bleeding that does not stop. If bleeding occurs, treatment must be stopped and surgery or fresh frozen plasma transfusions may be required. In life threatening situation, administration of blood clotting medicines such as prothrombin complex concentrates or recombinant factor VIIa, may be considered.

Administration of activated charcoal may be useful in the management of apixaban overdose or accidental ingestion.

While you are taking APICOG

-Things you must do

It is important that you continue taking APICOG daily as prescribed by your doctor.

Tell all the doctors, dentists and pharmacists treating you that you are taking APICOG.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

Tell your doctor immediately if you become pregnant while taking this medication

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give APICOG to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

APICOG tablet contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking APICOG.

Driving and using machines

APICOG has no or negligible influence on the ability to drive and use machines. If you are affected, do not drive or use machines.

Side Effects

Like all medicines, APICOG can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The following side effects are common if you take APICOG to prevent stroke or a blood clot from forming in the heart in patients with an irregular heartbeat and at least one additional risk factor.

- deficiency of red cells or of hemoglobin in the blood
- bleeding in your eyes, stomach, gums, nose or rectum
- blood found in the urine
- bruising and swelling
- localized collection of blood outside the blood vessel
- bleeding inside the body through a ruptured blood vessel
- low blood pressure (including fall in blood pressure during any medical procedure)
- nausea
- increase in Gamma-glutamyl transferase (an enzyme present in body)

The following side effects are common if you take APICOG to prevent blood clots in veins after a hip or knee replacement surgery.

- deficiency of red cells or of hemoglobin in the blood
- bleeding inside the body through a ruptured blood vessel
- localized collection of blood outside the blood vessels
- nausea
- bruising and swelling

The following side effects are common if you take APICOG to treat blood clots occurring in deep veins and clots in your lungs and also to prevent these from recurring.

- deficiency of red cells or of hemoglobin in the blood
- low platelet level in blood
- bleeding in your nose, stomach, gums, rectum
- abnormal bleeding from urinary tract, vagina or other reproductive organs
- bleeding inside the body through a ruptured blood vessel
- localized collection of blood outside the blood vessels
- blood in the urine
- bruising and swelling
- nausea
- skin rash
- increase in gamma glutamyl transferase and alanine aminotransferase (enzymes present in body)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of APICOG

-Storage

Store at a temperature not exceeding 30° C.

-Disposal

Do not take this medicine after the expiry date stamped on the pack.

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Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

-What it looks like

APICOG-2.5

Yellow, round shaped, biconvex, film coated tablets debossed with "11" on one side and plain on the other side.

APICOG-5

Pink, oval shaped, biconvex, film coated tablets debossed with "12" on one side and plain on the other side.

-Ingredients

Active Ingredient

APICOG-2.5

Each tablet contains 2.5 mg apixaban.

APICOG-5

Each tablet contains 5 mg apixaban.

Inactive ingredients

APICOG-2.5

Lactose anhydrous,
microcrystalline cellulose,
Croscarmellose sodium, sodium
lauryl sulfate, magnesium stearate,
Opadry II Yellow, purified water.

APICOG-5

Lactose anhydrous,
microcrystalline cellulose,
Croscarmellose sodium, sodium
lauryl sulfate, magnesium stearate,
Opadry II Pink, purified water.

-MAL Number

APICOG-2.5

MAL24086025AZ

APICOG-5

MAL24086026AZ

Manufacturer

Unison Pharmaceutical Pvt Ltd
Unit-III, C-7,8,9, Steel Town, Opp.
Nova Petrochemicals, Village
Moraiya, Sanand, Ahmedabad,
Gujarat 382213, India.

Product Registration Holder

Celestema Pharma Sdn. Bhd.
BO1-A-9 Menara 2, KL Eco City,
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