APIXTRA 5 (Apixaban Film-Coated Tablets 5 mg)

Apixaban (5mg)

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What APIXTRA is used for

APIXTRA 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:
    - previous stroke condition 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 ≥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.

APIXTRA 5 cannot be cut into two equal doses. APIXTRA 5 is not able to deliver the 2.5mg doses. Therefore, other approved dosage form and strength of Apixaban should be used in such cases.

How APIXTRA works

The active substance in APIXTRA is apixaban. It helps to prevent blood clot formation by inhibiting Factor Xa, which is an important component of blood clotting.

Before you use APIXTRA

- When you must not use it

Do not take APIXTRA if:

- you are allergic to Apixaban or to any of the other ingredients listed at the end of this leaflet
- you have an injury to a body organ or any internal bleeding
- you have liver disease associated with a bleeding disorder called coagulopathy and an increased risk of bleeding
- you 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)
- you are taking medicines to prevent blood clotting like heparins, heparin derivatives, warfarin, rivaroxaban and dabigatran
- you have severe kidney disease or kidney failure or if you are undergoing treatment (dialysis).

Pregnancy and lactation

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

It is not known if APIXTRA 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 APIXTRA.

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

- Before you start to use it

Talk to your doctor or pharmacist regarding these before taking APIXTRA:

- if you have any condition with increased risk of bleeding that affect your ability to form clots
- if you have atrial fibrillation along with other conditions that requires mono or dual antiplatelet therapy
- if you are undergoing procedures such as spinal/epidural anaesthesia or puncture and treated with antithrombotic agents to prevent clot
- if you have a prosthetic heart valve
- if you need to have surgery or a procedure which may cause bleeding
- if you have cancer
- if you have any kidney or liver disease
- if you are an elderly whose body weight is less than 60 kg
- if you are having hip fracture surgery
- if you have to undergo any clotting tests
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots),
- if you have hereditary problems of galactose intolerance
- if you are taking acetylsalicylic acid (ASA) as it increases the risk for bleeding in patients treated with APIXTRA.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- 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 norepinephrine re-uptake inhibitors

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- other medicines used to prevent blood clots such as enoxaparin, clopidogrel, prasugrel, dipyridamole, dextran, and sulfinpyrazone
- medicines for high blood pressure or heart problems (e.g., diltiazem, amiodarone, verapamil, quinidine, atenolol, digoxin)
- other antibiotics like clarithromycin
- other medicines such as famotidine and activated charcoal

How to use APIXTRA

- How much to use

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 Apixaban 2.5 mg 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 heartbeat:
The recommended dose is one tablet of Apixaban 5 mg twice a day.

The recommended dose reduction is 2.5 mg 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 10 mg Apixaban 5mg 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 2.5 mg 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 Apixaban: Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking Apixaban.

Changing from Apixaban to anticoagulant treatment containing vitamin K antagonist (e.g., warfarin): If your doctor tells you that you have to start taking the medicine containing a vitamin K antagonist, continue to take Apixaban 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 Apixaban.

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

If you require cardioversion before completing 5 doses of Apixaban, 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 Apixaban as prescribed before undergoing cardioversion.

You can continue using Apixaban 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 Apixaban.

- When to use it

Swallow the tablet(s) whole with a glass of water, with or without food. If you are unable to swallow whole tablets, Apixaban 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 the first tablet as directed by your doctor. Take your medicine at about the same time each day.

- How long to use it

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

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, 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.

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- If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use 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 Apixaban. 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 using it
- Things you must do
Take your medicine exactly as your doctor has told you.

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

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 APIXTRA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines

APIXTRA has no or negligible influence on the ability to drive and use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects
Like all medicines, APIXTRA 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 Apixaban 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 Apixaban 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 Apixaban 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 APIXTRA
- Storage
Keep out of the sight and reach of children. Store below 30°C.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
White to off white film coated tablet, oval, biconvex tablets debossed with ‘A40’ on one side and ‘H’ on other side.

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- Ingredients

- Active ingredient

Each film-coated tablet contains
5.0 mg Apixaban

- Inactive ingredients

Tablet core: Anhydrous Lactose, Microcrystalline Cellulose, Croscarmellose Sodium, Sodium Lauryl Sulfate, Magnesium Stearate.

Tablet film-coat: Purified Water, Opadry II White (32K580000) which consists of Hypromellose (E464), Lactose Monohydrate, Titanium Dioxide (E171), Triacetin.

- MAL number

MALXXXXXXXXAZ

Manufacturer
Hetero Labs Limited (Unit V)
Unit V, Sy. No.: 439, 440, 441 & 458,
Tsiic Formulation Sez, Polepally Village,
Mahabubnagar, Telangana, 509301, India.

Product Registration Holder
Camber Laboratories Sdn Bhd
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