Patient Information Leaflet

SCHEDULING STATUS

S4

EPLIPIX 2,5 film-coated tablets

EPLIPIX 5 film-coated tablets

Apixaban

Contains sugar:

EPLIPIX 2,5: Lactose 38,7 mg per tablet

EPLIPIX 5: Lactose 77,4 mg per tablet

Read all of this leaflet carefully before you start taking EPLIPIX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPLIPIX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in the leaflet

1. What EPLIPIX is and what it is used for
2. What you need to know before you take EPLIPIX
3. How to take EPLIPIX
4. Possible side effects
5. How to store EPLIPIX
6. Contents of the pack and other information

1. What EPLIPIX is and what it is used for

The active substance in EPLIPIX is apixaban.

Apixaban belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

EPLIPIX is used in adults:

- to prevent blood clots from forming after hip or knee replacement operations. After an operation to the hip or knee you may be at a higher risk of developing blood clots in your leg veins. This can cause the legs to swell, with or without pain.
- to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.

2. What you need to know before you take EPLIPIX

Do not take EPLIPIX

- if you are allergic to apixaban or any of the other ingredients of EPLIPIX (listed in section 6).
- if you are bleeding excessively.
- if you have a kidney disease.
- if you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy).
- if you have a disease in an organ of the body that increases the risk of serious bleeding (such as an active or a recent ulcer of your stomach or bowel, recent bleeding in your brain).
- if you have any disease or injury to a body organ that is actively bleeding or at high risk of bleeding e.g. bleeding ulcer in the stomach or bowel, recent bleeding in the brain, abnormalities of any blood vessels that may lead to an increase in bleeding, any blood vessel abnormalities of oesophagus, a recent operation on the brain, spinal column or eye(s).
- if you are taking medicines that act against blood clotting (e.g. clopidogrel) or medicines that prevent blood clotting (e.g, warfarin, rivaroxaban, dabigatran or heparin), except when changing anticoagulant treatment, while having a venous or arterial line and you get heparin through this line to keep it open, or if a tube is inserted into your blood vessel (catheter ablation) to treat an irregular heartbeat (dysrhythmia).

Warnings and precautions

Special care should be taken with EPLIPIX:

Tell your doctor before you take this medicine if you have any of the following:

- if you have an increased risk of bleeding, such as: bleeding disorders, including conditions resulting in reduced platelet activity; very high blood pressure, not controlled by medical treatment; you are older than 75 years; you weigh 60 kg or less.
- if you have a severe kidney disease or if you are on dialysis.
- if you have a liver problem or a history of liver problems.
- if you have a prosthetic heart valve.
- if your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.
- 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), tell your doctor who will decide if the treatment may need to be changed.
- if you need to have surgery or a procedure which may cause bleeding, your doctor might ask you to temporarily stop taking this medicine for a short while. If you are not sure whether a procedure may cause bleeding ask your doctor.

Children and adolescents

EPLIPIX is not recommended in children and adolescents under 18 years of age.

Other medicines and EPLIPIX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may increase the effects of EPLIPIX and some may decrease its effects. Your doctor will decide, if you should be treated with EPLIPIX when taking these medicines and how closely you should be monitored.

The following medicines may increase the effects of EPLIPIX and increase the chance for unwanted bleeding:

- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole, voriconazole and posaconazole etc.)
- antiviral medicines for HIV/AIDS (e.g. ritonavir)
- medicines used to reduce blood clotting (e.g. enoxaparin, clopidogrel, aspirin, etc.)
- anti-inflammatory or pain medicines (e.g. aspirin or naproxen). Especially, if you are older than 75 years and are taking aspirin, you may have an increased chance of bleeding.
- medicines for high blood pressure or heart problems (e.g. diltiazem)
- other medicines such as amiodarone, clarithromycin (an antibiotic), fluconazole, quinidine, verapamil
- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin norepinephrine re-uptake inhibitors (e.g. sertraline, citalopram and venlafaxine)

The following medicines may reduce the ability of EPLIPIX to help prevent blood clots from forming:

- medicines to prevent epilepsy or seizures (e.g. phenytoin, carbamazepine, phenobarbitone etc.)
- St John's Wort (a herbal supplement used for depression)
- medicines to treat tuberculosis or other infections (e.g. rifampicin)

EPLIPIX with food, drink and alcohol

EPLIPIX can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The effects of EPLIPIX on pregnancy and the unborn child are not known. You should not take EPLIPIX if you are pregnant.

It is not known if EPLIPIX passes into human breast milk. You should not breast-feed and take EPLIPIX at the same time. EPLIPIX is not recommended for mothers who are breastfeeding their infants

Driving and using machines

It is not always possible to predict to what extent EPLIPIX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EPLIPIX affects them.

EPLIPIX contains lactose

EPLIPIX contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking EPLIPIX.

3. How to take EPLIPIX

Do not share medicines prescribed for you with any other person.

Always take EPLIPIX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take EPLIPIX as recommended for the following:

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

The recommended dose is one tablet of EPLIPIX 2,5 mg twice a day. For example, one in the morning and one in the evening.

You should take the first tablet 12 to 24 hours after your operation.

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.

To prevent a blood clot from forming in the heart in patients with an irregular heartbeat and at least one additional risk factor

The recommended dose is one tablet of EPLIPIX 2,5 mg twice a day, for example, one in the morning and one in the evening, if:

- you have severely reduced kidney function
- two or more of the following apply to you:
  - your blood test results suggest poor kidney function (value of serum creatinine is 1,5 mg/dL (133 micromol/L or greater)
  - you are 80 years old or older
  - your weight is 60 kg or lower

Your doctor will decide how long you must continue treatment for.

Your doctor might change your anticoagulant treatment as follows:

- *Changing from* EPLIPIX *to anticoagulant medicines*

Stop taking EPLIPIX. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.

- *Changing from anticoagulant medicines to* EPLIPIX

Stop taking the anticoagulant medicines. Start treatment with EPLIPIX at the time you would have had the next dose of anticoagulant medicine, then continue as normal.

- *Changing from treatment with anticoagulant containing vitamin K antagonist (e.g. warfarin) to* EPLIPIX

Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking EPLIPIX.

- *Changing from* EPLIPIX *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 EPLIPIX 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 EPLIPIX.

If you take more EPLIPIX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take EPLIPIX

If you forget to take EPLIPIX, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking EPLIPIX

Do not stop taking your medicine without consulting your doctor.

4. Possible side effects

EPLIPIX can have side effects.

Not all side effects reported for EPLIPIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPLIPIX, please consult your health care provider for advice.

If any of the following happens, stop taking EPLIPIX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the skin, hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EPLIPIX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- any form of bleeding (e.g. from the mouth, eyes, nose, anus, coughing up blood, blood in the urine, blood in the stools, etc.),
- abnormal liver function tests presenting with symptoms such as yellowing of the skin and whites of the eyes, pain or swelling in the abdomen, loss of appetite, dark urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- a condition in which there is a decreased number of red blood cells in your blood and can present with symptoms such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale,
- low blood pressure including feeling dizzy when standing up too quickly,
- nausea,
- bruising.

Less frequent side effects:

- fever,
- loss of hair.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EPLIPIX.

5. How to store EPLIPIX

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPLIPIX contains

The active substance is apixaban.

The other ingredients are: croscarmellose sodium, hypremellose, iron oxide red (EPLIPIX 5), iron oxide yellow (EPLIPIX 2,5), lactose monohydrate, microcrystalline cellulose, magnesium stearate, povidone, sodium lauryl sulphate, titanium dioxide, triacetin

What EPLIPIX looks like and contents of the pack

EPLIPIX 2,5

Light yellow to yellow coloured round shaped film coated tablets debossed with “A1” on one side and plain on the other side.

EPLIPIX 5

Light pink to pink coloured oval shaped film coated tablets debossed with “A3” on one side and plain on the other side.

60 tablets or 180 tablets are packed in a round, opaque white/off-white HDPE bottle closed with a child-resistance closure with a heat seal and pulp liner for induction seal with a polyester coil.
10 tablets (for **EPLIPIX 2,5**) and 7 tablets (for **EPLIPIX 5**) are packed in a clear PVC film laminated with PVDC coat and aluminium foil with heat seal lacquer coating foil as lidding material.

Holder of Certificate of Registration

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