

Approved Patient Information Leaflet for Medicines for Human Use:

APIXABAN 2,5 mg AUSTELL

APIXABAN 5 mg AUSTELL

SCHEDULING STATUS: S4

APIXABAN 2,5 mg and 5 mg AUSTELL film-coated tablets

Apixaban

Contains sugar:

APIXABAN 2,5 mg AUSTELL film-coated tablets

Each 2,5 mg film-coated tablet contains 50,50 mg of anhydrous lactose.

APIXABAN 5 mg AUSTELL film-coated tablets

Each 5 mg film-coated tablet contains 101,00 mg of anhydrous lactose.

Read all of this leaflet carefully before you start taking APIXABAN AUSTELL

- 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.
- APIXABAN AUSTELL 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 this leaflet

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

1. What APIXABAN AUSTELL is and what it is used for

APIXABAN 2,5 mg and 5 mg AUSTELL tablets contains the active substance apixaban and 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.

APIXABAN AUSTELL is used in adults:

- to prevent blood clots (deep vein thrombosis [DVT]) 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. If a blood clot travels from your leg to your lungs, it can block blood flow causing breathlessness, with or without chest pain. This condition (pulmonary embolism) can be life-threatening and requires immediate medical attention.
- to prevent a blood clot from forming in the heart in patients with an irregular heartbeat (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 travel 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 APIXABAN AUSTELL

Do not take APIXABAN AUSTELL

- if you are hypersensitive (allergic) to apixaban or any of the other ingredients of APIXABAN AUSTELL (listed in section 6)
- if you are bleeding excessively
- if you have a severe kidney disease or if you are on dialysis
- if you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
- if you are taking antiplatelet medicines to prevent blood clotting (e.g. clopidogrel, ticagrelor, enoxaparin, dalteparin, warfarin, rivaroxaban, dabigatran) other than aspirin, 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)
- 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).

Warnings and precautions

Take special care with APIXABAN AUSTELL:

- if you have an increased risk of bleeding, such as:
 - bleeding disorders, including conditions resulting in reduced platelet activity
 - an active or a recent ulcer of your stomach or bowel
 - infection of the heart (bacterial endocarditis)
 - recent bleeding in your brain (haemorrhagic stroke)
 - very high blood pressure, not controlled by medical treatment
 - a recent operation on your brain, spinal column or eye
 - you are older than 75 years
 - you weigh 60 kg or less
- a severe kidney disease or if you are on dialysis

- a liver problem or a history of liver problems. Your doctor will perform a test on your liver function before you take APIXABAN AUSTELL and it will be used with caution in patients with signs of altered liver function
- 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 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 undergo surgery your doctor might ask you to temporarily stop taking APIXABAN AUSTELL.

Children and adolescents

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

Other medicines and APIXABAN AUSTELL

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 APIXABAN AUSTELL and some may decrease its effects. Your doctor will decide if you should be treated with APIXABAN AUSTELL when taking these medicines and how closely you should be monitored.

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

- some medicines for fungal infections (ketoconazole, etc.)
- some antiviral medicines for HIV/AIDS (e.g. ritonavir)

- other medicines that are used to reduce blood clotting (e.g. enoxaparin, clopidogrel, etc.)
- anti-inflammatory or pain medicines (e.g. aspirin or Non-steroidal Anti-inflammatory Drugs (NSAIDS))
- medicines for high blood pressure or heart problems (e.g. diltiazem)
- antidepressants belonging to the classes called Selective Serotonin Reuptake Inhibitors (SSRIs e.g. citalopram, fluoxetine, sertraline, etc.) and Serotonin Norepinephrine Reuptake Inhibitors (SNRIs e.g. duloxetine, venlafaxine etc.)
- NSAIDS called non-steroid anti-inflammatory drugs (used to treat pain and inflammation) (e.g. naproxen)
- some antibiotics (used to treat bacterial infections) (e.g. clarithromycin).

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

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

APIXABAN AUSTELL with food and drink

APIXABAN AUSTELL can be taken with or without food.

Pregnancy and breastfeeding

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 APIXABAN AUSTELL on pregnancy and the unborn child are not known. Treatment may increase the risk of bleeding during pregnancy and delivery.

You should not take APIXABAN AUSTELL if you are pregnant. Contact your doctor immediately if you become pregnant while taking APIXABAN AUSTELL.

It is not known if APIXABAN AUSTELL passes into human breast milk. Do not take APIXABAN AUSTELL while breastfeeding.

Driving and using machines

It is not always possible to predict to what extent APIXABAN AUSTELL 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 APIXABAN AUSTELL affects them.

APIXABAN AUSTELL contains lactose

APIXABAN AUSTELL contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking APIXABAN AUSTELL.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take APIXABAN AUSTELL

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

Always take APIXABAN AUSTELL exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet twice a day.

Method of administration

- You can take APIXABAN AUSTELL with or without food.

- Swallow the tablet with a drink of water.

If you are unable to swallow whole tablets you may crush the tablets and add it to water, apple juice or mix it with applesauce. This should be taken immediately.

Duration of administration

Your doctor will tell you how long your treatment with APIXABAN AUSTELL will last.

If you take more APIXABAN AUSTELL than you should

If you take more APIXABAN AUSTELL than recommended, you may have an increased risk of bleeding. If bleeding occurs, surgery, blood transfusions, or other treatments that may reverse anti-factor Xa activity may be required.

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 APIXABAN AUSTELL

Take APIXABAN AUSTELL as soon as you remember and take the next tablet of APIXABAN AUSTELL at the usual time and then continue as normal.

If you stop taking APIXABAN AUSTELL

Do not stop taking APIXABAN AUSTELL without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early.

4. Possible side effects

APIXABAN AUSTELL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- bleeding:
 - in your brain or in your spinal column
 - in your eyes
 - in your mouth or blood in your spit when coughing
 - into your abdomen, or from the vagina
 - bright/red blood in the stools
 - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
 - into a muscle
 - from a haemorrhoid
 - tests showing blood in the stools or in the urine (or seeing that the colour of your urine is pink or red)
 - bruising.

These are very serious side effects. If you have them, you may have had a serious reaction to APIXABAN AUSTELL. 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:

- anaemia which may cause tiredness or paleness
- reduced number of platelets in your blood (which can affect clotting)
- rapid swelling of the deep layers of skin where the swelling feels like large, thick, firm welts and can cause redness, pain, or warmth in the swollen areas
- blood tests that may show:
 - abnormal liver function
 - an increase in some liver enzymes
 - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes
 - an increase in gamma-glutamyltransferase (GGT)
- low blood pressure which may make you feel faint or have a quickened heartbeat.

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:

- nausea (feeling sick)

Less frequent side effects:

- itching
- hair loss.

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 or nurse. 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 APIXABAN AUSTELL.

5. How to store APIXABAN AUSTELL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original packaging until required for use.
- Do not use after the expiry date stated on the label/carton/bottle after EXP. The expiry date refers to the last day of that month.

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 APIXABAN AUSTELL contains

- The active substance is apixaban.
- The other ingredients are:

APIXABAN 2,5 mg AUSTELL film-coated tablets:

Anhydrous lactose

Cellulose, microcrystalline (PH 102)

Croscarmellose sodium

Sodium lauryl sulfate

Magnesium stearate

Opadry II 32K520162 Yellow

Purified Water

APIXABAN 5 mg AUSTELL film-coated tablets:

Anhydrous lactose

Cellulose, microcrystalline (PH 102)

Croscarmellose sodium

Sodium lauryl sulfate

Magnesium stearate

Opadry II 32K540099 Pink

Purified Water

What APIXABAN 2,5 mg and 5 mg AUSTELL looks like and contents of the pack

APIXABAN 2,5 mg AUSTELL film-coated tablets

Yellow, round shaped, approximate 6,00 mm in diameter, biconvex, film-coated tablet debossed with "IU1" on one side and plain on the other side.

APIXABAN 5 mg AUSTELL film-coated tablets

Pink, oval shaped, approximate 9,8 mm in length, 5,2 mm in width, biconvex, film coated tablet debossed with "IU2" on one side and plain on other side.

APIXABAN AUSTELL film-coated tablets are packed in clear PVC/PVDC-Alu blisters and/or white opaque HDPE bottles.

PVC/PVDC-Aluminium blisters are available in 10, 14, 20, 28, 56, 60, 100, 112, 168, and 200 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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