PATIENT INFORMATION LEAFLET FOR XARPIX 2,5 / XARPIX 5

SCHEDULING STATUS: S4

XARPIX 2,5 mg (Film-coated tablets)

XARPIX 5 mg (Film-coated tablets)

Apixaban

Each film-coated tablet of the XARPIX 2,5 contains 50,50 mg lactose monohydrate.

Each film-coated tablet of the XARPIX 5 contains 101,00 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking XARPIX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your medical practitioner, pharmacist, nurse or other health care provider.
- XARPIX 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 XARPIX is and what it is used for

2. What you need to know before you take XARPIX

3. How to take XARPIX

4. Possible side effects

5. How to store XARPIX

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1. What XARPIX is and what it is used for

XARPIX contains the active substance called apixaban. This belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots by blocking Factor Xa, which is an important component of blood clotting.

XARPIX is used in adults

- 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.
- to treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.
- 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 lugs, it can block blood flow causing breathlessness, with or without chest pain. This condition (pulmonary embolism [PE]) can be life-threatening and requires immediate medical attention.

2. What you need to know before you take XARPIX

Do not take XARPIX if:

- you are allergic (hypersensitive) to apixaban or any of the excipients of XARPIX (listed in section 6)
- you are bleeding excessively or prone to bleeding excessively (haemophilia or other bleeding disorders)
- you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
- you are taking antiplatelet medicines (e.g clopidogrel, ticagrelor) other than aspirin
- you have severe kidney disease, or you are on dialysis
- you suffer from a condition called antiphospholipid syndrome, a disorder of the immune system that causes an increased risk of blood clots.

Warnings and precautions

Tell your medical practitioner or health care provider before you take this medicine if you have any of the following:

- 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
  - an active or recent stomach or bowel ulcer
  - recent bleeding in your brain (haemorrhagic stroke)
  - infection of the heart (bacterial endocarditis)
  - a recent operation on your brain, spinal column or eye
- a liver problem or history of liver problems;

  Your medical practitioner will perform a test on your liver enzymes before you take XARPIX and it will be used with caution should you have signs of altered liver function.
- a severe kidney disease or if you are on dialysis;
- if you have a prosthetic heart valve;

- know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots);
- had a tube (catheter) or an injection into your spinal column (for anesthesia or pain reduction), your medical practitioner will tell you to take XARPIX 6 hours or more after catheter removal.

If you need to have surgery or a procedure which may cause bleeding, your medical practitioner might ask you to temporarily stop taking this medicine. If you are not sure whether a procedure may cause bleeding ask your medical practitioner.

Children and adolescents

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

Other medicines and XARPIX

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)
The use of XARPIX with these medicines may cause undesirable interactions.

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

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

- some medicines for fungal infections (e.g., ketoconazole, etc);

- some antiviral medicines for HIV / AIDS (e.g., ritonavir);
- other medicines that are used to reduce blood clotting (e.g., enoxaparin, 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);
- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin norepinephrine re-uptake inhibitors.

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

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

If you are taking any of these medicines, your medical practitioner may change your XARPIX therapy if you are using XARPIX for treatment or prevention of DVT or PE.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your medical practitioner, pharmacist or health care professional for advice before taking this medicine.

The effects of XARPIX on pregnancy and the unborn child are not known. You should not take this medicine if you are pregnant. Contact your medical practitioner immediately if you become pregnant while taking this medicine.

It is not known if XARPIX passes into human breast milk. Ask your medical practitioner, pharmacist or health care professional for advice before taking this medicine while breast-feeding.

Driving and using machines

XARPIX has not been shown to impair your ability to drive or use machines.

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

XARPIX contains lactose

XARPIX contains lactose (milk sugar). If you have been told by your medical practitioner that you have an intolerance to some sugars, contact your medical practitioner before taking this medicine.

3. How to take XARPIX

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

Always take XARPIX exactly as your medical practitioner has told you. Check with your medical practitioner or pharmacist if you are not sure.

XARPIX can be taken with or without food.

Swallow the tablet with a drink of water.

The usual dose is one tablet twice a day, every day for as long as your medical practitioner tells you to take XARPIX. Take the tablets at the same time every day for example one in the morning and one in the evening.

Your medical practitioner will tell you the strength of the tablet depending on why it has been prescribed for you.

If you have the impression that the effect of XARPIX is too strong or too weak, talk to your medical practitioner or pharmacist.

If you take more XARPIX than you should

Tell your medical practitioner immediately if you have taken more than the prescribed dose of XARPIX. Take the medicine pack with you even if there are no tablets left.
If you take more XARPIX than recommended you may have an increased risk of bleeding. If bleeding occurs, surgery or blood transfusion may be required.

Your medical practitioner may administer activated charcoal to you which may be useful if you have taken XARPIX accidently or taken more than you should have.

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

If you forget to take XARPIX

- Take it as soon as you remember it and take the next tablet at the usual time.
- However, if is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for forgotten individual doses.

- If you are not sure what to do or have missed more than one dose, ask your medical practitioner or pharmacist.

If you stop taking XARPIX

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

If you have any further questions on the use of XARPIX, ask your medical practitioner or pharmacist.

4. Possible side effects

XARPIX can have side effects.

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

If any of the following happens stop taking XARPIX and tell your medical practitioner immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing
- skin rash, itching

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

Tell your medical practitioner immediately or go to the casualty department at your nearest hospital if you notice:

Any type of bleeding including:

- bleeding from your nose
- blood in the stools
- blood found in the urine (that stains the urine pink or red)
- bleeding from your vagina
- bleeding from a wound after surgery
- bleeding gums
- coughing or vomiting up blood
- severe and sudden headache with numbness or tingling on one side of your body – may indicate a brain bleed
- pain, heat, swelling and/or tightness, tingling together with difficulty moving the joint or limb may indicate a muscle bleed

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

Frequent side effects:

- Anaemia which may cause tiredness or paleness;
- Nausea (feeling sick);
- Blood tests may show:
    - an increase in gamma-glutamyltransferase (GGT).
    - abnormal liver function;
    - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.

Less frequent side effects:

- Low blood pressure
- Hair loss

- Reduced number of platelets in your blood (which can affect clotting) you may notice bruising, bleeding under the skin.
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https//www.sahpra.org.za/documents/adverse-drug-reactions-and-quality-problem-reporting-form/

Suspected adverse reactions can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or the email address: adverse.event.sac@sandoz.com.

5. How to store XARPIX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep blisters enclosed in cardboard carton until required for use.

6. Contents of the pack and other information

What XARPIX contains

The active substance is apixaban. Each film-coated tablet contains 2,5 mg or 5 mg apixaban.

The other ingredients are:

Lactose monohydrate

Cellulose, microcrystalline

Croscarmellose sodium

Sodium laurylsulfate

Magnesium stearate

Hypromellose (type 2910)

Hydroxypropylcellulose

Macrogols 6000

Titanium dioxide (E171)

Iron oxide, yellow (E172)

What XARPIX looks like and contents of the pack

XARPIX 2,5 (Film-coated tablets)

Yellow, round, biconvex, film coated tablet, debossed AX on one side and 2,5 on the other side.

XARPIX 5 (film-coated tablets)

Pink, oval, biconvex, film coated tablet, debossed AX on one side and 5 on the other side.

XARPIX film-coated tablets are packed into an PVC/PVDC/Aluminium blister pack.

Pack sizes:

The available pack sizes are 60’s and 100’s

Not all pack sizes are marketed

The blisters are packed together with the leaflet into the cardboard carton.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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Registration numbers

XARPIX 2,5: 56/8.2/0627.625

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Access to the corresponding Professional Information

TBA

[1]Company Reg. No.: 1990/001979/07