PATIENT INFORMATION LEAFLET

AXOLTA RANGE

SCHEDULING STATUS

S4

AXOLTA 10 mg film coated tablets

AXOLTA 15 mg film coated tablets

AXOLTA 20 mg film coated tablets

Rivaroxaban

AXOLTA contains sugar (lactose 53,57 mg, 80,36 mg, 107,14 mg per tablet respectively).

Essentially 'sodium free'

Read all of this leaflet carefully before you start taking AXOLTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AXOLTA 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 AXOLTA is and what it is used for
2. What you need to know before you take AXOLTA
3. How to take AXOLTA
4. Possible side effects
5. How to store AXOLTA
6. Contents of the pack and other information

1. What AXOLTA is and what it is used for

Rivaroxaban belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

AXOLTA 10 mg is indicated for:

- prevention of blood clots in the veins after a hip or knee replacement operation. Your doctor has prescribed this medicine for you because after an operation if you are at an increased risk of getting blood clots.

AXOLTA 15 and 20 mg is indicated to:

- prevent blood clots in the brain (stroke) and other blood vessels in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation
- 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.

2. What you need to know before you take AXOLTA

Do not take AXOLTA:

- if you are hypersensitive (allergic) to rivaroxaban, or to any of the ingredients of AXOLTA (see section 6)
- if you are currently bleeding excessively or have an inherited bleeding disorder
- if you have a disease or condition in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you have a liver disease which leads to an increased risk of bleeding
- if you are pregnant or breast-feeding your baby.

Warnings and precautions

Take special care with AXOLTA:

- if you have a prosthetic heart valve
- if you have an increased risk of bleeding, as could be the case in situations such as:

  - severe kidney disease, since your kidney function may affect the amount of medicine that works in your body
  - if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open (see section Other medicines and AXOLTA)
  - bleeding disorders
  - very high blood pressure, not controlled by medical treatment
  - diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus (gullet), e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus)
  - a problem with the blood vessels in the back of your eyes (retinopathy)
  - a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or previous bleeding from your lung
- if you have kidney disease
- if you are taking certain antifungal medicines (e.g. ketoconazole, itraconazole, voriconazole and posaconazole) or HIV treatment (e.g. ritonavir)
- if you are taking nonsteroidal anti-inflammatory medicines (NSAIDs) for pain or other medicines to prevent blood clots
- 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 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 are an elderly patient, you may be at higher risk of bleeding so your doctor may want to monitor you more closely

- if you experience any form of severe skin rash (e.g. spreading, intense and/or blistering) or hypersensitivity symptoms.

If any of the above apply to you, tell your doctor before you take AXOLTA. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If you need to have an operation

- it is very important to take AXOLTA before and after the operation exactly at the times you have been told by your doctor
- if your operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
    - it is very important to take AXOLTA before and after the injection or removal of the catheter exactly at the times you have been told by your doctor
    - tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

Other medicines and AXOLTA

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

If you are taking any of the following medicines, tell your doctor before taking AXOLTA, because the effect of AXOLTA may be increased. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, he/she may also use a preventative ulcer treatment.

- ketoconazole, (used to treat fungal infections)
- other fungal infections (e.g. fluconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin

- ritonavir (used to treat HIV / AIDS)
- clarithromycin and erythromycin (antibiotics used to treat bacterial infections)
- dronedarone, a medicine to treat abnormal heartbeat
- enoxaparin, clopidogrel or vitamin K antagonists such as warfarin and acenocoumarol (used to reduce blood clotting)
- naproxen or acetylsalicylic acid (anti-inflammatory and pain-relieving medicines)
- citalopram, escitalopram, fluoxetine, paroxetine, vortioxetine, fluvoxamine (some medicines to treat depression called selective serotonin reuptake inhibitors (SSRIs); or serotonin noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine, desvenlafaxine and duloxetine.

If any of the following apply to you, tell your doctor before taking AXOLTA, because the effect of AXOLTA may be reduced.
Your doctor will decide, if you should be treated with AXOLTA and if you should be kept under closer observation:

- rifampicin (an antibiotic used to treat tuberculosis)
- phenytoin, carbamazepine, phenobarbital (used to treat epilepsy)
- St John's Wort (*Hypericum perforatum*), a herbal product used for depression

AXOLTA with food and drink

AXOLTA 15 mg and 20 mg are to be taken with food.

AXOLTA 10 mg 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 healthcare provider for advice before using AXOLTA.

Do not take AXOLTA if you are pregnant or breastfeeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking AXOLTA. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

AXOLTA may cause dizziness or fainting (see section 4, Possible side effects).
It is not always possible to predict to what extent AXOLTA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which AXOLTA affects you.

AXOLTA contains lactose

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

Sodium

Axolta contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

3. How to take AXOLTA

Do not share medicines prescribed for you with any other person. Always use AXOLTA exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Adults:

AXOLTA 10 mg:

To prevent blood clots in the veins after a hip or knee replacement operation:

The recommended dose is one tablet AXOLTA 10 mg once a day.

AXOLTA 15 mg and 20 mg:

To prevent blood clots in the brain (stroke) and other blood vessels in your body:

The recommended dose is one tablet AXOLTA 20 mg once a day. If you have kidney problems, the dose may be reduced to one tablet AXOLTA 15 mg once a day.

To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs, and for preventing blood clots from re-occurring:

The recommended dose is one tablet AXOLTA 15 mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet AXOLTA 20 mg once a day.
Your doctor may decide to continue treatment with one 20 mg tablet once a day for as long as required.

Children:

AXOLTA is not recommended for use in children.

Your doctor will tell you how long your treatment with AXOLTA will last. Do not stop treatment early because symptoms may return.
If you have the impression that the effect of AXOLTA is too strong or too weak, tell your doctor or pharmacist.

If you take more AXOLTA than you should

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

Symptoms of overdose may include:

- increased bleeding.

If you forget to take AXOLTA

If you are taking one 20 mg tablet or one 15 mg tablet once a day and have missed a dose, take it as soon as you remember. Do not take more than one tablet in a single day to make up for a forgotten dose. Take the next tablet on the following day and then carry on taking one tablet once a day.

If you are taking one 10 mg tablet and have missed a dose, take it as soon as you remember. Take the next tablet on the following day and then carry on taking a tablet once a day as normal.
Do not take a double dose to make up for a forgotten tablet.

If you are taking one 15 mg tablet twice a day and have missed a dose, take it as soon as you remember. If you forget to take a dose, you can take two 15 mg tablets at the same time to get a total of two tablets (30 mg) on one day. On the following day you should carry on taking one 15 mg tablet twice a day.

If you stop taking AXOLTA

Do not stop taking AXOLTA without talking to your doctor first, because AXOLTA treats and prevents serious conditions.

4. Possible side effects

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

AXOLTA may cause bleeding which may potentially be life threatening. Excessive bleeding may lead to sudden drop in blood pressure (shock). In some cases, the bleedings may not be obvious.
If any of the following happens, stop using AXOLTA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain (angina pectoris). These may be signs of bleeding (haemorrhage).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AXOLTA. 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:

- bleeding into the brain or inside the skull (symptoms such as sudden weakness, tingling, or paralysis of face, arm or leg, change in vision, severe headache, nausea or vomiting)
- irregular or fast heartbeat (tachycardia)
- kidney failure after a severe bleeding
- yellowing of the skin and eyes caused by liver or blood problems (jaundice)
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite)
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), Toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin)
- a medicine reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome)

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:

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- dizziness, headache
- bleeding into the eye (including bleeding from the whites of the eyes)
- low blood pressure (symptoms may be feeling dizzy or fainting when standing up), bleeding into tissue or a cavity of the body (haematoma, bruising), oozing of blood or fluid from surgical wound
- nosebleed, coughing up blood
- bleeding in the stomach or bowel, bleeding gums, stomach ache, indigestion, nausea, vomiting, constipation, diarrhoea
- severe itching of the skin (pruritus), rash, bruising, bleeding from the skin or under the skin
- painful legs/arms
- urogenital bleeding (including blood in the urine and heavy menstrual bleeding), impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever, swollen lower legs or hands, decreased general strength and energy (weakness, tiredness)
- blood tests may show an increase in some liver enzymes
- bleeding following an operation

Less frequent side effects:

- high platelet count in the blood (thrombocytosis) seen in blood test results
- bleeding into the tissues and slow blood clotting after injury (thrombocytopenia)
- dry mouth
- cholestasis (decreased bile flow)
- skin rash, rash of round, red welts on the skin that itch intensely, sometimes with dangerous

swelling (urticaria)

- bleeding into a joint causing pain and swelling, bleeding into the muscle
- general feeling of discomfort, illness, or unease, swelling due to excessive fluid accumulation
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets

The following side effects have been reported but the frequency for them to occur is not known:

- increased pressure within muscles of the legs or arms after a bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after a bleeding)

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found
on the SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.
By reporting side effects, you can help provide more information on the safety of AXOLTA.

5. How to store AXOLTA

Store all medicines out of reach of children.

Store at or below 25 °C, protect from light and moisture.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton. 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 AXOLTA contains:

AXOLTA 10 mg: each film coated tablets contains rivaroxaban 10 mg.

Contains sugar (lactose monohydrate 53,57 mg per tablet).

AXOLTA 15 mg: each film coated tablets contains rivaroxaban 15 mg.

Contains sugar (lactose monohydrate 80,36 mg per tablet).

AXOLTA 20 mg: each film coated tablets contains rivaroxaban 20 mg.

Contains sugar (lactose monohydrate 107,14 mg per tablet).

The other ingredients are:

Tablet cores:

Croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate

Film coating – Opadry Pink (10 mg)/Brown (15 mg)/White (20 mg):

Hypromellose, iron oxide red (10 mg and 15 mg), macrogol, titanium dioxide.

What AXOLTA looks like and contents of the pack

AXOLTA 10 mg are light pink coloured, round shaped, biconvex, film coated tablets debossed with "LU" on one side and "R76" on the other side.

AXOLTA 15 mg are reddish brown coloured, round shaped, biconvex, film coated tablets debossed with "LU" on one side and "R77" on the other side.

AXOLTA 20 mg are white coloured, round shaped, biconvex, film coated tablets debossed with "LU" on one side and "R78" on the other side.

AXOLTA tablets are available clear PVC/PVDC blister packs with printed aluminium foil backing, packed in a printed outer cartons containing 30 tablets (10 and 20 mg) or 45 tablets (15 mg).

Holder of Certificate of Registration

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