Bayer (Pty) Ltd

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IXAROLA® 10 Film-coated tablets
Rivaroxaban
Contains sugar (lactose)

Read all of this leaflet carefully before you start taking IXAROLA 10

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- IXAROLA 10 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 IXAROLA 10 is and what it is used for
2. What you need to know before you take IXAROLA 10
3. How to take IXAROLA 10
4. Possible side effects
5. How to store IXAROLA 10
6. Contents of the pack and other information

1. What IXAROLA 10 is and what it is used for

IXAROLA 10 is used to prevent blood clots in your veins after a major operation on your legs. For example, this could be an operation on your hip or knee. Your doctor has prescribed IXAROLA 10 for you because after an operation you are at an increased risk of getting blood clots.
The active substance is rivaroxaban. It belongs to a group of medicines called antithrombotic agents. It works by inhibiting blood clotting Factor Xa.

2. What you need to know before you take IXAROLA 10

Do not take IXAROLA 10 and tell your doctor if any of the following apply to you:

- **if you are allergic** (hypersensitive) to rivaroxaban or any of the other ingredients of IXAROLA 10
- **if you are bleeding excessively**
- **if you have severe liver disease** which leads to an increased risk of bleeding
- **if you are pregnant or breast feeding**

Warnings and precautions

Take special care with IXAROLA 10:

- if you have **severe kidney disease**
- if you have **an increased risk of bleeding** such as:
  - **bleeding disorders**
  - **very high blood pressure,** not controlled by medical treatment

- **active ulcer or a recent ulcer** of your stomach or bowel
- **a problem with the blood vessels in the back of your eyes** (retinopathy)
- **recent bleeding in your brain** (intracranial or intracerebral bleeding)
- **a recent operation on your brain, spinal column or eye**

Tell your doctor before you take IXAROLA 10, if any of these apply to you. Your doctor may decide to keep you under closer observation.

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 IXAROLA 10 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.

Children and adolescents

IXAROLA 10 is **not recommended for people under 18 years of age.** There is not enough information on its use in children and adolescents.

Other medicines and IXAROLA 10

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of IXAROLA 10 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

If you are taking:

- some **medicines for fungal infections** (e.g. ketoconazole), unless they are only applied to the skin
- **anti-viral medicines for HIV/AIDS** (e.g. ritonavir)
- other medicines to **reduce blood clotting** (e.g. enoxaparin or clopidogrel)
- **anti-inflammatory and pain-relieving medicines** (e.g. naproxen or acetylsalicylic acid)

Tell your doctor before taking IXAROLA 10, because its effect may be increased. Your doctor may decide to keep you under closer observation.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while taking IXAROLA 10, please consult your doctor, pharmacist or other healthcare professional for advice.

If you are pregnant or breastfeeding don't take IXAROLA 10. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking IXAROLA 10. If you become pregnant while you are taking IXAROLA 10, immediately tell your doctor who will decide how you should be treated.

Driving and using machines

IXAROLA 10 may cause side effects such as dizziness or fainting (see "Possible side effects"). You should not drive or use machines if you are affected by these symptoms.

IXAROLA 10 contains lactose

Patients with rare hereditary problems of lactose or galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption, who are on a lactose-free diet, should take this into consideration.

3. How to take IXAROLA 10

Do not share medicines prescribed for you with others.
Always take IXAROLA 10 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take
The usual dose is one IXAROLA 10 tablet (10 mg) once a day.
Swallow the tablet preferably with water.
IXAROLA 10 tablet can be taken with or without food.

When to take IXAROLA 10
Take the first tablet 6 - 10 hours after your operation.
Then take a tablet every day until your doctor tells you to stop.
Try to take the tablet at the same time every day to help you to remember it.
If you have had a major hip operation you will usually take the tablets for 5 weeks.
If you have had a major knee operation you will usually take the tablets for 2 weeks.

If you take more IXAROLA 10 than you should

Contact your doctor immediately if you have taken too many IXAROLA 10 tablets. Taking too much IXAROLA 10 increases the risk of bleeding.
Please consult your doctor or pharmacist in the case of accidental overdose. If neither is available, rush the patient to the nearest hospital or poison control center.

If you forget to take IXAROLA 10

If you 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 stop taking IXAROLA 10

Don’t stop taking IXAROLA 10 without talking to your doctor first, because IXAROLA 10 prevents the development of a serious condition.
If you have any further questions on the use of IXAROLA 10, ask your doctor or pharmacist.

4. Possible side-effects

Not all side-effects reported for IXAROLA 10 are included in this leaflet. Should your general health worsen while taking IXAROLA 10, please consult your doctor, pharmacist or other healthcare professional for advice.

IXAROLA 10 can cause side-effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), IXAROLA 10 may cause bleedings In some cases these bleedings may not be obvious.

Tell your doctor, if you experience any of the following side-effects**:**

- **long or excessive bleeding**
- **exceptional weakness, tiredness, paleness, dizziness, headache, ~~or~~ unexplained swelling,**

Your doctor may decide to keep you under closer observation or change how you should be treated.
The following side-effects have been reported for IXAROLA 10:

Frequent side effects

- bleeding following your operation
- anaemia (reduction in the quantity of oxygen-carrying material (haemoglobin) in the blood)
- feeling sick (nausea)
- blood tests may show an increase in some liver enzymes

Less frequent side effects

- bleeding in your stomach or bowel, genital bleeding, nose bleed
- haematoma (an accumulation of blood within the tissue that clots to form a solid swelling), bruising
- blood in your urine
- oozing from surgical wound
- raised heart beat (tachycardia)
- low blood pressure
- feeling unwell (weakness, tiredness), headache, dizziness, fainting
- stomach ache, indigestion (constipation, diarrhoea, dyspepsia (gastric indigestion), vomiting)
- dry mouth
- localised swelling, swelling in your limbs (oedema)
- fever
- pain in your limbs
- rash, itchy skin, hives
- impaired function of your kidneys
- blood tests may show an increase in bilirubin, some pancreatic enzymes or in the number of platelets (thrombocythaemia)
- impaired function of your liver
- allergic skin reactions

In addition, the following side-effects have been reported for IXAROLA 10: adrenal bleeding, bleeding from the whites of your eyes or bleeding from a stomach ulcer leading to death, yellowing of the skin and eye (jaundice), hypersensitivity and coughing blood.

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. This includes any possible side effects not listed in this leaflet. 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 IXAROLA 10.

5. How to store IXAROLA 10

Keep out of the reach and sight of children.
Store at or below 30 °C. Keep blister strips in the original carton until use.
Do not use IXAROLA 10 after the expiry date which is stated on the carton and on each blister.
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 IXAROLA 10 contains

The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban. Contains lactose.
The other ingredients are:
Tablet core: cellulose microcrystalline, croscarmellose sodium, hydroxypropylmethylcellulose 2910, lactose monohydrate, magnesium stearate, sodium laurylsulfate,
Film coat: ferric oxide red, hydroxypropylmethylcellulose 2910, polyethylene glycol, titanium dioxide.

What IXAROLA 10 looks like and contents of the pack

IXAROLA 10 film-coated tablets are light red, round, biconvex tablets, 6 mm in diameter, debossed with "Triangle 10" on the top side and the BAYER-cross on the bottom side of the tablet.

IXAROLA 10 film-coated tablets are packed in colourless, transparent PP (polypropylene)/aluminium blister strips or colourless, transparent PVC/PVDC/aluminium blister strips containing 5 or 10 tablets per blister.
Pack sizes: 5 tablets (1 x 5's blister), 10 tablets (1 x 10's blister), 30 tablets (3 x 10's blister) or 100 tablets (10 x 10's blister).
Not all pack sizes may be marketed.

Holder of certificate of registration

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