PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

APIXABAN 2,5 DRL film-coated tablets

APIXABAN 5 DRL film-coated tablets

Apixaban

Contains sugar

(lactose 76,84 mg and 153,68 mg respectively)

Read all of this leaflet carefully before you start taking APIXABAN DRL film-coated tablets

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

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

APIXABAN DRL 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 DRL is used in adults:

- to prevent blood clots (venous thromboembolic events (VTE)) 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.
- 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 (DVT)) and in the blood vessels of your lungs (pulmonary embolism (PE)), 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 APIXABAN DRL

Do not take APIXABAN DRL if you:

- are allergic (hypersensitive) to apixaban or any of the other ingredients of APIXABAN DRL (see section 6).
- are bleeding excessively.
- have kidney disease.
- have a liver disease which leads to increased risk of bleeding.
- are taking medicines to prevent blood clotting (e.g., warfarin, rivaroxaban, dabigatran or heparin).
- you suffer from a condition called antiphospholipid syndrome (APS) with persistent positivity for all three antiphospholipid antibodies.

Warnings and precautions

Special care should be taken with APIXABAN DRL:

- 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 in the heart, high blood pressure which is not controlled by medical treatment, a history of bleeding in the brain and recent brain/spinal or eye surgery;
- if you are taking medicines which prevent blood clotting (e.g., warfarin), medicines called selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), or non-steroidal anti-inflammatory drugs (NSAIDs), or aspirin;
- if you have a prosthetic heart valve;

- 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 APIXABAN DRL for a short while. If you are not sure whether a procedure may cause bleeding ask your doctor;
- if you temporarily stop your treatment of APIXABAN DRL;
- if you had a tube (catheter) or an injection into your spinal column (for anaesthesia or pain reduction), your doctor will tell you to take APIXABAN DRL 5 hours or more after catheter removal;
- 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 are elderly;
- if you have a low body weight (i.e., < 60 kg);
- if you are taking antifungal medicines such as ketoconazole, itraconazole, voriconazole posaconazole or ritonavir (a medicine used to treat HIV);
- if you are taking medicines such as rifampicin, phenytoin, carbamazepine, phenobarbital or St. John's Wort;
- if you undergoing hip fracture surgery.

Children and adolescents

APIXABAN DRL is not for use in children and adolescents under 18 years of age.

Other medicines and APIXABAN DRL

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Taking APIXABAN DRL with some medicines may mean the doctor will need to change your dose of APIXABAN DRL or the other medicines.

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

- medicines for fungal infections (e.g., ketoconazole, itraconazole, voriconazole and posaconazole) and anti-bacterials (e.g., clarithromycin);
- antiviral medicines for HIV/AIDS (e.g., ritonavir);
- medicines for high blood pressure or heart problems (e.g., diltiazem);
- anti-inflammatory or pain medicines (e.g., acetylsalicylic acid or naproxen). Especially, if you are older than 75 years and are taking acetylsalicylic acid, you may have an increased chance of bleeding;
- other medicines that are used to reduce blood clotting (e.g., enoxaparin);
- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin norepinephrine re-uptake inhibitors.

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

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

These medicines may increase the risk of side effects or reduce the effect of APIXABAN DRL. If you get any unusual symptom taking any of these medicines together with APIXABAN DRL you should see your doctor.

APIXABAN DRL with food and drink

APIXABAN DRL can be taken with or without food.

Pregnancy, breastfeeding and fertility

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

APIXABAN DRL may cause harm to your unborn child if you are taking it while being pregnant.

You should not take APIXABAN DRL if you are breastfeeding.

Driving and using machines

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

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

APIXABAN DRL contains lactose

APIXABAN DRL contains lactose (which is 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 DRL.

3. How to take APIXABAN DRL

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

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

Do not change the dose or stop taking APIXABAN DRL without talking with your doctor or pharmacist.

Talk with your doctor about how long you should keep on taking APIXABAN DRL.

APIXABAN DRL is for oral use.

You should swallow your tablet whole with a glass of water.

APIXABAN DRL can be taken with or without food.

Try to take the tablets at the same times every day to have the best treatment effect.

Take APIXABAN DRL as recommended for the following:

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

The recommended dose is one tablet of APIXABAN DRL 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 heart beat and at least one additional risk factor

The recommended dose is one tablet of APIXABAN DRL 5 mg twice a day.

The recommended dose is one tablet of APIXABAN DRL 2,5 mg twice a day if:

- you have severely reduced kidney function

To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs

The recommended dose is two 5 mg tablets twice a day for the first 7 days, for example, two in the morning and two in the evening. After 7 days the recommended dose is one 5 mg tablet twice a day.

For preventing blood clots from re-occurring following completion of 6 months of treatment

The recommended dose is one 2,5 mg tablet twice a day for example, one in the morning and one in the evening. Your doctor will decide how long you must continue your treatment.

Your doctor might change your anticoagulant treatment as follows:

- *Changing from APIXABAN DRL to anticoagulant medicines*

  Stop taking APIXABAN DRL. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.
- *Changing from anticoagulant medicines to APIXABAN DRL*

  Stop taking the anticoagulant medicines. Start treatment with APIXABAN DRL 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 APIXABAN DRL*

  Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking APIXABAN DRL.
- *Changing from APIXABAN DRL 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 APIXABAN DRL 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 APIXABAN DRL.

Your doctor will tell you how long your treatment with APIXABAN DRL will last.
Even if you feel better, do not alter or discontinue the daily dose of APIXABAN DRL without first consulting your doctor.

If you have the impression that the effect of APIXABAN DRL is too strong or too weak, tell your doctor or pharmacist.

If you take more APIXABAN DRL than you should

Tell your doctor immediately if you have taken more than the prescribed dose of APIXABAN DRL.
Take the medicine pack with you, even if there are no tablets left.
If you take more APIXABAN DRL 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.
Your doctor may administer activated charcoal to you which may be useful if you have taken APIXABAN DRL accidently or taken more than you should have.
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 DRL

Take the dose as soon as you remember and:

- take the next dose of APIXABAN DRL at the usual time
- then continue as normal

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 doctor, pharmacist or other healthcare provider.

If you stop taking APIXABAN DRL

- Do not stop taking APIXABAN DRL without talking to your doctor 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 this product, ask your doctor or pharmacist.

4. Possible side effects

APIXABAN DRL can have side effects.

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

APIXABAN DRL can be given for different medical conditions. The known possible side effects and how frequently they occur for each of these medical conditions may differ and are listed separately below.

The most common general possible side effect of APIXABAN DRL is bleeding which may be potentially life-threatening and require immediate medical attention.

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

- swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing;
- throat tightness, shortness of breath and wheezing.

Allergic reactions, including death, can happen in patients taking APIXABAN DRL even after only one dose.

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

APIXABAN DRL causes bleeding which may be potentially life threatening and require immediate medical attention.

<u>The following side effects are known if you take APIXABAN DRL to prevent blood clots from forming after hip or knee replacement operations:</u>

Frequent side effects:

- Anaemia (low iron levels in blood) which may cause tiredness or paleness;
- Bleeding including swelling;
- Nausea (feeling sick);
- Bruising.

Less frequent side effects:

- Reduced number of platelets in your blood (which can affect clotting);
- Itching;
- Bleeding in the eye, nose, gums, lungs, stomach, bowel, muscles, vagina, bright red blood in the stools, dark coloured stools, blood in the urine;
- Low blood pressure which may make you feel faint or have a quickened heartbeat;
- Coughing up and/or vomiting of blood;
- Blood tests 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;
- Hair loss;
- Blood or liquid leaking from the surgical wound/incision (wound secretion, bleeding at the catheter site).

Side effects of unknown frequency:

- Angioedema (swelling of areas of tissue under your skin);
- Bleeding:
  - in your brain or in your spinal column;
  - in your lungs or your throat;
  - in your mouth;
  - into your abdomen or space behind your abdominal cavity;

- from a haemorrhoid;
- tests showing blood in the stools or in the urine;

- Skin rash;
- Inflamed blood vessels in the skin;
- Type of acute kidney injury that may be caused by excessive anti-clotting effects with warfarin and other anti-clotting medicines.

<u>The following side effects are known if you take APIXABAN DRL to prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor:</u>

Frequent side effects:

- Anaemia (low iron levels in blood) which may cause tiredness or paleness;
- Bleeding in the eye and nose;
- Low blood pressure which may make you feel faint or have a quickened heartbeat;
- Bleeding in gums, stomach, bowel, bright red blood in the stools, dark coloured stools, vomiting blood, nausea (feeling sick);
- Blood tests may show:
  - an increase in gamma-glutamyltransferase (GGT);
- Blood in the urine;
- Bruising.

Less frequent side effects:

- Reduced number of platelets in your blood (which can affect clotting);
- Bleeding in your brain or in your spinal column, stomach, mouth, rectum, lungs, muscles;

- Vomiting of blood;
- Blood tests 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;
- Skin rash, hair loss;
- Blood or liquid leaking from the surgical wound/incision (wound secretion, bleeding at the catheter site.

Side effects of unknown frequency:

- Angioedema (swelling of areas of tissue under your skin);
- Inflamed blood vessels in the skin;
- Type of acute kidney injury that may be caused by excessive anti-clotting effects with warfarin and other anti-clotting medicines.

<u>The following side effects are known if you take APIXABAN DRL to treat or prevent re-occurrence of blood clots in the veins of your legs and blood clots in the blood vessels of your lungs</u>

Frequent side effects:

- Anaemia which may cause tiredness or paleness;
- Reduced number of platelets in your blood (which can affect clotting);
- Bleeding including:
  - bruising and swelling;

- from your nose;
- into your abdomen;
- from your mouth;
- from your rectum;
- from your gums;
- blood in the urine;
- from the vagina;

- Nausea (feeling sick);
- Blood tests may show an increase in some liver enzymes;
- Skin rash.

Less frequent side effects:

- Itching;
- Bleeding including:
  - in your eyes;
  - blood in your spit when coughing;
  - from a haemorrhoid;
  - bright/red blood in the stools;
  - into a muscle;
  - bleeding including bruising and swelling, blood or liquid leaking from the surgical wound or from the injection site;
  - blood found in the urine on laboratory testing;
  - in your brain;
  - in our lungs;

- Low blood pressure which may make you feel faint or have a quickened heartbeat;
- Blood tests 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;
- Hair loss.

Side effects of unknown frequency:

- Angioedema (swelling of areas of tissue under your skin);
- Bleeding into your abdomen or the space behind your abdominal cavity.

If you notice any side effects not on this leaflet, please inform you doctor 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of APIXABAN DRL.

5. How to store APIXABAN DRL

Store at or below 25 °C.

Keep the container tightly closed.

Keep all medicines out of reach and sight of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not store in bathrooms.

Do not use after the expiry date stated on the bottle/carton.

6. Contents of the pack and other information

What APIXABAN DRL contains

The active substance is apixaban.

APIXABAN 2,5 DRL: Each film-coated tablet contains 2,5 mg apixaban.

APIXABAN 5 DRL: Each film-coated tablet contains 5 mg apixaban.

The other ingredients for the tablet core are anhydrous lactose, croscarmellose sodium, isopropyl alcohol, hypromellose 5 CPS (methocel E5 premium), magnesium stearate, methylene chloride, microcrystalline cellulose, sodium lauryl sulphate.

The ingredients of the film coat are lactose monohydrate, HPMC 2910/Hypromellose 15 mPas, titanium dioxide and triacetin.

What APIXABAN DRL looks like and contents of the pack

APIXABAN 2,5 DRL: White to off white colored, round shaped, biconvex, film coated tablet, debossed with '2.5' on one side and 'Y'(logo) on the other side.

APIXABAN 5 DRL: White to off white colored, oval shaped, biconvex, film coated tablet, debossed with '5' on one side and 'Y'(logo) on the other side.

APIXABAN 2,5 DRL: HDPE bottles containing pack sizes of 60's or 180's.

APIXABAN 5 DRL: HDPE bottles containing pack sizes of 60's or 180's.

Not all pack sizes are marketed.

This leaflet was last revised in

16 October 2024

Registration numbers

APIXABAN 2,5 DRL: 56/8.2/0106

APIXABAN 5 DRL: 56/8.2/0107

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories website:

http://www.drreddys.co.za