

Applicant/HCR: Accord Healthcare (Pty) Ltd

APIXABAN ACCORD 2,5/5 (Film-coated tablets)

Strength: Each film-coated tablet contains 2,5 mg and 5 mg Apixaban

Initial submission: 19/11/2020 (0000)

Clinical screening query as per SAHPRA email dated 10/06/2022: submitted 27/06/2022 (0002)

PEM unit response dated 23/08/2023 (0003)

Submission of Final PIL as per email received 12/10/2023: submitted 23/10/2023

FINAL PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S4

APIXABAN 2,5 ACCORD (Film-coated tablet)

APIXABAN 5 ACCORD (Film-coated tablet)

Apixaban

Contains sugar (lactose)

APIXABAN 2,5 ACCORD: Each film-coated tablet contains 51,97 mg lactose.

APIXABAN 5 ACCORD: Each film-coated tablet contains 103,95 mg lactose

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

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

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

- **APIXABAN ACCORD** contains the active substance apixaban.
- It 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 2,5 ACCORD** 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.

- **Apixaban 2,5 Accord** and **APIXABAN 5 ACCORD** 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

2. What you need to know before you use APIXABAN ACCORD

Do not take APIXABAN ACCORD:

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- if you are hypersensitive (allergic) to apixaban or any of the other ingredients of **APIXABAN ACCORD** (listed in section 6).
- If you are bleeding excessively
- 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)
- If you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
- If you are taking medicines to prevent blood clotting (e.g., warfarin, rivaroxaban, dabigatran or heparin), 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 (arrhythmia).

Warnings and precautions

Special care should be taken with **APIXABAN ACCORD** 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
- you are older than 65 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

APIXABAN ACCORD will be used with caution in patients with signs of altered liver function.

- had a tube (catheter) or an injection into your spinal column (for anaesthesia or pain reduction), your doctor will tell you to take **APIXABAN ACCORD** 5 hours or more after catheter removal

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- 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

Take special care with APIXABAN ACCORD

- 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 this medicine for a short while. If you are not sure whether a procedure may cause bleeding ask your doctor.

Children and adolescents

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

Other medicines and APIXABAN ACCORD

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

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The following medicines may increase the effects of **APIXABAN ACCORD** 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., acetylsalicylic acid or naproxen). Especially, if you are older than 65 years and are taking acetylsalicylic acid, 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 **APIXABAN ACCORD** to help prevent blood clots from forming:

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

Pregnancy and breast-feeding

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 ACCORD** on pregnancy and the unborn child are not known. You should not take **APIXABAN ACCORD** if you are pregnant. Contact your doctor immediately if you become pregnant while taking **APIXABAN ACCORD**.

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It is not known if **APIXABAN ACCORD** passes into human breast milk. Ask your doctor, pharmacist or nurse for advice before taking this medicine while breast-feeding. They will advise you to either stop breast-feeding or to stop/not start taking **APIXABAN ACCORD**.

Driving and using machines

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

APIXABAN ACCORD 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 this medicinal product.

3. How to take APIXABAN ACCORD

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

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

Dose

Swallow the tablet with a drink of water. **APIXABAN ACCORD** can be taken with or without food.

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

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take **APIXABAN ACCORD**. The tablet may be crushed and mixed with water, or 5 % dextrose in water, or apple juice or apple puree, immediately before you take it.

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Instructions for crushing:

- Crush the tablets with a pestle and mortar.
- Transfer all the powder carefully into a suitable container then mix the powder with a little e.g., 30 mL (2 tablespoons), water or one of the other liquids mentioned above to make a mixture.
- Swallow the mixture.
- Rinse the pestle and mortar you used for crushing the tablet and the container, with a little water or one of the other liquids (e.g., 30 mL), and swallow the rinse.

If necessary, your doctor may also give you the crushed **APIXABAN ACCORD** tablet mixed in 60 mL of water or 5 % dextrose in water, through a nasogastric tube.

Your doctor will tell you how long your treatment with **APIXABAN ACCORD** will last. If you have the impression that the effect of **APIXABAN ACCORD** is too strong or too weak, tell your doctor or pharmacist.

Take APIXABAN ACCORD 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 ACCORD** 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 heartbeat and at least one additional risk factor.

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

The recommended dose is one tablet of **APIXABAN ACCORD** 2.5 mg twice a day if:

- you have severely reduced kidney function
- two or more of the following apply to you:
 - your blood test results suggest poor kidney function (value of serum creatinine is 1.5 mg/dL (133 micromole/L) or greater)
 - you are 80 years old or older
 - your weight is 60 kg or lower.

The recommended dose is one tablet twice a day, for example, one in the morning and one in the evening.

Your doctor will decide how long you must continue treatment for.

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 tablets of **APIXABAN ACCORD** 5 mg 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 tablet of **APIXABAN ACCORD** 5 mg twice a day, for example, one in the morning and one in the evening.

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

The recommended dose is one tablet of **APIXABAN ACCORD** 2.5 mg twice a day for example, one in the morning and one in the evening.

Your doctor will decide how long you must continue treatment for.

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Your doctor might change your anticoagulant treatment as follows:

- *Changing from **APIXABAN ACCORD** to anticoagulant medicines*

Stop taking **APIXABAN ACCORD**. 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 ACCORD***

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

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

Changing from **APIXABAN ACCORD** 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 ACCORD** 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 ACCORD**.

Patients undergoing cardioversion

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take **APIXABAN ACCORD** at the times your doctor tells you, to prevent blood clots in blood vessels in your brain and other blood vessels in your body.

If you take more APIXABAN ACCORD than you should:

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In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you, even if there are no tablets left.

If you take more **APIXABAN ACCORD** 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.

If you forget to take APIXABAN ACCORD

- Take the dose as soon as you remember and:
- take the next dose of **APIXABAN ACCORD** at the usual time
- then continue as normal

If you stop taking APIXABAN ACCORD

Do not stop taking **APIXABAN ACCORD** 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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

APIXABAN ACCORD can have side effects.

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

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The following side effects are known if you take **APIXABAN ACCORD** to prevent blood clots from forming after hip or knee replacement operations.

Frequent side effects

- Anemia which may cause tiredness or paleness
- Bleeding including:
 - bruising and swelling
 - Nausea (feeling sick)

Less frequent side effects

- Reduced number of platelets in your blood (which can affect clotting)
- Bleeding:
 - occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
 - in your stomach, bowel or bright/red blood in the stools
 - blood in the urine
 - from your nose
 - from the vagina
- 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.
- Itching

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Less frequent side effects

- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms.

- Bleeding:

- into a muscle

- in your eyes

- from your gums and blood in your spit when coughing

- from your rectum

- Hair loss

Frequency unknown

- 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 hemorrhoid

- tests showing blood in the stools or in the urine

- Skin rash

The following side effects are known if you take **APIXABAN ACCORD** to prevent a blood clot from forming in the heart in patients with an irregular heartbeat and at least one additional risk factor.

Frequent side effects

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- Bleeding including:

- in your eyes

- in your stomach or bowel

- from your rectum

- blood in the urine

- from your nose

- from your gums

- bruising and swelling

- Anemia which may cause tiredness or paleness

- Low blood pressure which may make you feel faint or have a quickened heartbeat

- Nausea (feeling sick)

Blood tests may show:

- an increase in gamma-glutamyltransferase (GGT)

Less frequent side effects

- Bleeding:

- in your brain or in your spinal column

- 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

- from a hemorrhoid

- tests showing blood in the stools or in the urine

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- Reduced number of platelets in your blood (which can affect clotting)
- 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
- Itching
- Hair loss
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms.

Less frequent side effects

- Bleeding:
 - in your lungs or your throat
 - into the space behind your abdominal cavity
 - into a muscle

The following side effects are known if you take **APIXABAN ACCORD** 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.

Frequent side effects

- Bleeding including:
 - from your nose
 - from your gums

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- blood in the urine
- bruising and swelling
- in your stomach, your bowel, from your rectum
- in your mouth
- from the vagina
- Anemia which may cause tiredness or paleness
- Reduced number of platelets in your blood (which can affect clotting)
- Nausea (feeling sick)
- Skin rash
- Blood tests may show:
 - an increase in gamma-glutamyltransferase (GGT) or alanine aminotransferase (ALT)

Less frequent side effects

- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Bleeding:
 - in your eyes
 - in your mouth or blood in your spit when coughing
 - bright/red blood in the stools
 - tests showing blood in the stools or in the urine
 - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
 - from a hemorrhoid
 - into a muscle
- Itching

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- Hair loss
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms.
- 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.

Less frequent side effects

Bleeding:

- in your brain or in your spinal column
- in your lungs

Frequency unknown

Bleeding:

- into your abdomen or the space behind your abdominal cavity

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>. 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

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information on the safety of **APIXABAN ACCORD**.

5. How to store APIXABAN ACCORD

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- There are no special storage instructions for **APIXABAN ACCORD**.
- Store in original package until use.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 ACCORD contains

- The active substance is apixaban.
- Each tablet contains 2.5 mg or 5 mg of apixaban.
- The other ingredients are
 - **Tablet core:**
 - Lactose
 - Cellulose, microcrystalline (PH 102)
 - Croscarmellose sodium
 - Sodium laurilsulfate
 - Magnesium stearate
 - **Film-coat:**
 - Hypromellose (15 mPas)

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- Lactose monohydrate
- Titanium dioxide (E171)
- Triacetin
- Iron oxide yellow (E172) (2,5 mg)
- Iron oxide red (E172) (5 mg)

What APIXABAN ACCORD looks like and contents of the pack

- **APIXABAN 2,5 ACCORD:** Yellow, round shaped, approximately 6,00 mm in diameter, biconvex, film coated tablet debossed with "IU1" on one side and plain on other side.
- **APIXABAN 5 ACCORD:** Pink, oval shaped, approximately 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.
- The film-coated tablets are packed in PVC/PVDC - Alu blisters packs or HDPE bottles
- Pack sizes: PVC/PVdC-Aluminium blisters are available in 10, 14, 20, 28, 56, 60, 100, 112, 168, and 200 film-coated tablets.
- HDPE bottle containing 60, 100, 168, 180, 200 and 1000 film-coated tablets.
- Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park,

6 Coombe Place

Rivonia

Johannesburg

South Africa

Applicant/HCR: Accord Healthcare (Pty) Ltd

APIXABAN ACCORD 2,5/5 (Film-coated tablets)

Strength: Each film-coated tablet contains 2,5 mg and 5 mg Apixaban

Initial submission: 19/11/2020 (0000)

Clinical screening query as per SAHPRA email dated 10/06/2022: submitted 27/06/2022 (0002)

PEM unit response dated 23/08/2023 (0003)

Submission of Final PIL as per email received 12/10/2023: submitted 23/10/2023

FINAL PATIENT INFORMATION LEAFLET (CLEAN COPY)

This leaflet was last revised in

03 October 2023

Registration number

APIXABAN 2,5 ACCORD : 55/8.2/0372

APIXABAN 5 ACCORD : 55/8.2/0373