

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

VIBANEX 2,5 mg Film-coated tablets

VIBANEX 5 mg Film-coated tablets

Apixaban

VIBANEX 2,5 mg: Contains sugar: Lactose anhydrous 51,75 mg

VIBANEX 5 mg: Contains sugar: Lactose anhydrous 103,5 mg

Read all of this leaflet carefully before you start taking VIBANEX

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

1. What VIBANEX is and what it is used for

VIBANEX 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.

VIBANEX 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 (PE)] can be life-threatening and requires immediate medical attention.
- To prevent a blood clot from forming in the heart in patients with an irregular heartbeat (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.

2. What you need to know before you take VIBANEX

Do not take VIBANEX

- If you are hypersensitive (allergic) to apixaban or any of the other ingredients of VIBANEX (listed in section 6).
- If you are bleeding excessively.
- If you have a severe kidney disease or if you are on dialysis.
- 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 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).
- If you suffer from a condition called antiphospholipid syndrome (APS) with persistent positivity for all three antiphospholipid antibodies.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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.
 - An active or a recent ulcer of your stomach or bowel.
 - Infection of the heart (bacterial endocarditis).
 - Recent bleeding in your brain (haemorrhagic stroke).
 - A recent operation on your brain, spinal column or eye.
 - Very high blood pressure, not controlled by medical treatment.
 - You are older than 75 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.
 - This medicine will be used with caution in patients with signs of altered liver function.
- 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.
- Had a tube (catheter) or an injection into your spinal column (for anaesthesia or pain reduction), your doctor will tell you to take VIBANEX 6 hours or more after catheter removal.

Take special care with VIBANEX:

- 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

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

Other medicines and VIBANEX

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

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

- Some medicines for fungal infections (e.g. ketoconazole, etc).
- Medicines used to treat infections (antibiotics) (e.g. clarithromycin).
- 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 75 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 VIBANEX 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).

VIBANEX with food and drink

VIBANEX can be taken with or without food.

Pregnancy and breastfeeding

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 VIBANEX on pregnancy and unborn child are not known.

Treatment may increase the risk of bleeding during pregnancy and delivery. You should not take this medicine if you are pregnant. Contact your doctor immediately if you become pregnant while taking this medicine.

It is not known if VIBANEX passes into human milk. Ask your doctor, pharmacist or nurse for advice

before taking this medicine while breastfeeding. They will advise you whether to stop breastfeeding or to stop/not start taking this medicine.

Driving and using machines

VIBANEX has no or negligible influence on the ability to drive and use machines.

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

VIBANEX 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 VIBANEX.

3. How to take VIBANEX

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

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

Swallow the tablet with a drink of water. VIBANEX can be taken with or without food.

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

Your doctor will tell you how long your treatment with VIBANEX will last. Try to take the tablets at the same times every day to have the best treatment effect.

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

Take VIBANEX as recommended for the following:

To prevent a blood clot from forming in the heart in patients with an irregular heartbeat (atrial fibrillation) and at least one additional risk factor

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

The recommended dose is one tablet of VIBANEX 2,5 mg twice a day:

- If you have severely reduced kidney function.
- If 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.

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

If you are undergoing cardioversion

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

Your doctor might change your anticoagulant treatment as follows:

- *Changing from VIBANEX to anticoagulant medicines*
Stop taking VIBANEX. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.
- *Changing from anticoagulant medicines to VIBANEX*
Stop taking the anticoagulant medicines. Start treatment with VIBANEX 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 VIBANEX*
Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking VIBANEX.
- *Changing from VIBANEX 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 VIBANEX 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 VIBANEX.

If you take more VIBANEX than you should

Tell your doctor immediately if you have taken more than the prescribed dose of VIBANEX. Take the medicine pack with you, even if there are no tablets left.

If you take more VIBANEX 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 VIBANEX accidentally 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 VIBANEX

Take the dose as soon as you remember and:

- take the next dose of VIBANEX 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 nurse.

If you stop taking VIBANEX

Do not stop taking this medicine 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 further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

VIBANEX can have side effects.

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

If any of the following happens, stop taking VIBANEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

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

VIBANEX. You may need urgent medical attention or hospitalisation.

The most common general side effect of this medicine is bleeding which may be potentially life threatening and require immediate medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bleeding from your nose.
- If you have dark brown urine or blood in your urine.
- If you cough up blood.
- If you vomit and it is black.
- If you have black stools or blood in your stools.
- Excessive bleeding or prolonged bleeding.

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

- Bleeding including:
 - In your eyes.
 - From your rectum.
 - From a haemorrhoid.
 - In your mouth or blood in your spit when coughing.
 - From your gums.
 - From the vagina.
 - Bruising and swelling.
- Anaemia which may cause tiredness or paleness.
- Reduced number of platelets in your blood (which can affect clotting).
- 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) (liver enzymes).
 - An increase in alanine aminotransferase (liver enzymes).

Less frequent side effects

- Bleeding:
 - In your brain or in your spinal column.
 - Into your abdomen.
 - In your lungs or your throat.
 - Into the space behind your abdominal cavity.
 - Into a muscle.
 - Bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site.
 - Bleeding after an injury.
- Blood tests may show:
 - Abnormal liver function.
 - An increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.
- Hair loss.

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

Reporting of side effects

If you get any 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 VIBANEX.

5. How to store VIBANEX

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not remove the blisters from the outer carton until required for use.
- Store in the original package.
- Protect from light/moisture.
- Do not store in a bathroom.

- Do not use after the expiry date stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 VIBANEX contains:

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

Uncoated tablet:

Cellulose microcrystalline (Avicel PH-113)

Croscarmellose sodium (Ac-di-sol)

Lactose anhydrous

Magnesium stearate

Sodium lauryl sulphate (Kolliphore SLS fine)

Film-coating:

Insta-coat Universal Brown (A05R04319):

Hypromellose

Polyethylene glycol

Red iron oxide

Sodium lauryl sulfate

Titanium dioxide

Yellow iron oxide

What VIBANEX looks like and contents of the pack

VIBANEX 2,5 mg: Brown, film-coated, round, biconvex, beveled edge tablet debossed with X 2 on one side of the tablet and M on other side.

VIBANEX 5 mg: Brown, film-coated, oval, biconvex, beveled edge tablet, debossed with X 5 on one side of the tablet and M on the other side.

VIBANEX 2,5 mg: PVC/PVDC blister pack comprising of clear, transparent PVC and hard tampered aluminium foil coated with heat seal lacquer. Packed in a carton. (1 blister of 10 film-coated tablets each). Pack sizes: 10's.

VIBANEX 5 mg: PVC/PVDC blister pack comprising of clear, transparent PVC and hard tampered aluminium foil coated with heat seal lacquer. Packed in a carton. (1 blister of 10 film-coated tablets each). Pack sizes: 10's

Holder of Certificate of Registration

Viatis South Africa (Pty) Ltd

4 Brewery Street

Isando

Kempton Park

Gauteng, 1601

Tel. no.: +2711 451 1300

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Registration numbers

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