

**Apixaban 1mg/ml Oral Suspension**



Read all of this leaflet carefully before you start taking this medicine - because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

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

**1. What Apixaban is and what it is used for**

The full name of your medicine is Apixaban 1mg/ml Oral Suspension. In this leaflet the shorter name Apixaban is used. Apixaban 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 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.
  - 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 take Apixaban Oral Suspension**

**Do not take Apixaban:**

- you are allergic to apixaban or any of the other ingredients of this medicine (listed in section 6);
- you are bleeding excessively;
- 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);
- you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy);
- 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**

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

- 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 Apixaban**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

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

The following medicines may increase the effects of Apixaban and increase the chance of 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 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 Apixaban 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).

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

The effects of Apixaban on pregnancy and the unborn child are not known. 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 Apixaban passes into human breast milk. Ask your doctor, pharmacist or nurse for advice before taking this medicine while breast-feeding. They will advise you whether to stop breast-feeding or to stop/not start taking this medicine.

**Driving and using machines**

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

Apixaban contains sorbitol and sodium benzoate:

- Sorbitol (E420). This medicine contains 200 mg of sorbitol in each ml.
- Sodium benzoate (E 211). This medicine contains 1 mg sodium benzoate in each ml.
- This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially "sodium-free".

**3. How to take Apixaban Oral Suspension**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

**Dose**

Apixaban can be taken with or without food. Take Apixaban Oral Suspension with a glass of water.

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

If necessary, your doctor may also give you Apixaban, through a nasogastric tube.

**Take Apixaban as recommended for the following:**

- To prevent blood clots from forming after hip or knee replacement operations. The recommended dose is 2.5 mg (2.5 ml) twice a day. For example, one in the morning and one in the evening. You should take the first dose 12 to 24 hours after your operation.
- If you have had a major hip operation you will usually take the oral suspension for 32 to 38 days.
- If you have had a major knee operation you will usually take the oral suspension 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 of Apixaban Oral Suspension is 5 mg (5 ml) twice a day.
- The recommended dose of Apixaban Oral Suspension is 2.5 mg (2.5 ml) 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 Apixaban Oral Suspension 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 of Apixaban Oral Suspension is 5 mg (5 ml) 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 of Apixaban Oral Suspension is 5 mg (5 ml) 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 of Apixaban Oral Suspension is 2.5 mg (2.5 ml) 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.

**Your doctor might change your anticoagulant treatment as follows:**

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

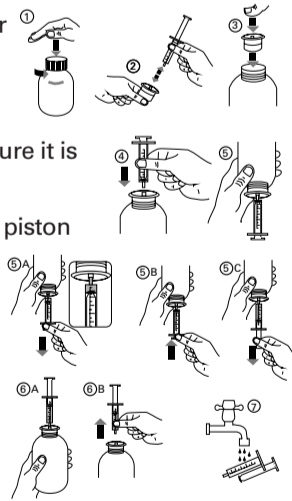
**Patients undergoing cardioversion**

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.

**Instructions for use**

The oral suspension must be shaken well before use.

- Open the bottle: press the cap and turn it anticlockwise (figure 1)
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).
- Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).
- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).
- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth.
- After dosing, wash the syringe with water only (figure 7).



**If you take more Apixaban than you should**

Tell your doctor immediately if you have taken more than the prescribed dose of Apixaban. Take the medicine pack with you, even if there are no oral suspension left. If you take more Apixaban 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**

- Take the dose of Apixaban as soon as you remember and:
  - take the next dose of Apixaban at the usual time;
  - then continue as normal.

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 Apixaban**

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 any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Apixaban can be given for three different medical conditions. The known side effects and how frequently they occur for each of these medical conditions may differ and are listed separately below. For these conditions, the most common general side effect of this medicine is bleeding which may be potentially life threatening and require immediate medical attention.

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

**Common side effects (may affect up to 1 in 10 people)**

- Anaemia which may cause tiredness or paleness;
- Bleeding including:
  - bruising and swelling;

- Nausea (feeling sick).

**Uncommon side effects (may affect up to 1 in 100 people)**

- 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.

**Rare side effects (may affect up to 1 in 1,000 people)**

- 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.

**Not known (frequency cannot be estimated from the available data)**

- 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 which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*);

- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

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

**Common side effects (may affect up to 1 in 10 people)**

- 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;

- Anaemia 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).

**Uncommon side effects (may affect up to 1 in 100 people)**

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

- 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.

**Rare side effects (may affect up to 1 in 1,000 people)**

- Bleeding:

- in your lungs or your throat;
- into the space behind your abdominal cavity;
- into a muscle.

**Very rare side effects (may affect up to 1 in 10,000 people)**

- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*).

**Not known (frequency cannot be estimated from the available data)**

- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

The following side effects are known if you take Apixaban 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.

**Common side effects (may affect up to 1 in 10 people)**

- Bleeding including:

- from your nose;
- from your gums;
- blood in the urine;
- bruising and swelling;
- in your stomach, your bowel, from your rectum;
- in your mouth;
- from the vagina;

- Anaemia 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).

**Uncommon side effects (may affect up to 1 in 100 people)**

- 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 any operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site;
- from a haemorrhoid;
- into a muscle;

- 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;

- 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.

**Rare side effects (may affect up to 1 in 1,000 people)**

- Bleeding:

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

**Not known (frequency cannot be estimated from the available data)**

- Bleeding:

- into your abdomen or the space behind your abdominal cavity.
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*);
- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.
- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store Apixaban Oral Suspension**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use 30 days after you first open it.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not use Apixaban if you notice anything wrong with the medicine. Talk to your doctor or pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Apixaban Oral Suspension contains**

- The active substance is apixaban. Each 1 ml of oral solution contains 1 mg of apixaban.
- The other ingredients are Sucralose (E995), Xanthan Gum (E415), Sodium Benzoate (E211), Citric Acid anhydrous (E330), Tri-sodium Citrate Dihydrate (E331), Simeicone emulsion 30% (E210), Sorbitol solution (E420), Glycerin (E422), Peppermint flavour (501524 1T)

**What Apixaban Oral Suspension looks like and contents of the pack**

Apixaban is an off-white oral suspension.

Apixaban oral suspension comes in a white opaque HDPE bottle with a white child resistant tamper evident expanded polypropylene (TE/PP) closure, containing 150 ml of liquid product.

The package contains a 5ml oral syringe with 1.25ml graduations together with a low-density polyethylene bottle adaptor.

**Patient Alert Card: handling information**

Inside the Apixaban pack together with the package leaflet you will find a Patient Alert Card or your doctor might give you a similar card.

This Patient Alert Card includes information that will be helpful to you and alert other doctors that you are taking Apixaban. **You should keep this card with you at all times.**

1. Take the card.

2. Complete the following sections or ask your doctor to do it:

- Name:
- Birth Date:
- Indication:
- Dose : .....mg twice daily
- Doctor's Name:
- Doctor's telephone:

3. Fold the card and keep it with you at all times.

**Marketing Authorisation Holder:**

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**This leaflet was last revised in 07/2025**

**If you would like the leaflet in an alternative format information (braille or large print), for blind and partially sighted patients, please contact marketing authorisation holder listed above.**