

Package leaflet: Information for the patient

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik Apixaban

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This leaflet has been written for the patients (“you”) and the parent or caregiver who will give this medicines to the child.

- 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is and what it is used for
2. What you need to know before you take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik
3. How to take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik
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1. What Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is and what it is used for

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 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.
- 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.

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is used in paediatric patients weighing ≥ 35 kg to treat blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs.

For body weight appropriate recommended dose, see section 3.

2. What you need to know before you take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Do not take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik if:

- **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**
Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

- 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 cannot be used in paediatric patients weighing < 35 kg since the provided syringe is not suitable for accurate dosing in these patients. For paediatric patients weighing <35 kg, alternative pharmaceutical forms may be available, such as apixaban granules in capsules or sachets. Healthcare professionals should consult the respective SmPC for these products.

Other medicines and Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik and some may decrease its effects. Your doctor will decide, if you should be treated with Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik when taking these medicines and how closely you should be monitored.

The following medicines may increase the effects of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik on pregnancy and the unborn child are not known. You should not take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik if you are pregnant. **Contact your doctor immediately** if you become pregnant while taking Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik.

It is not known if Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik.

Driving and using machines

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik has not been shown to impair your ability to drive or use machines.

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik contains sodium and sodium benzoate.

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik contains 1 mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik can be taken with or without food. Try to take the suspension at the same times every day to have the best treatment effect.

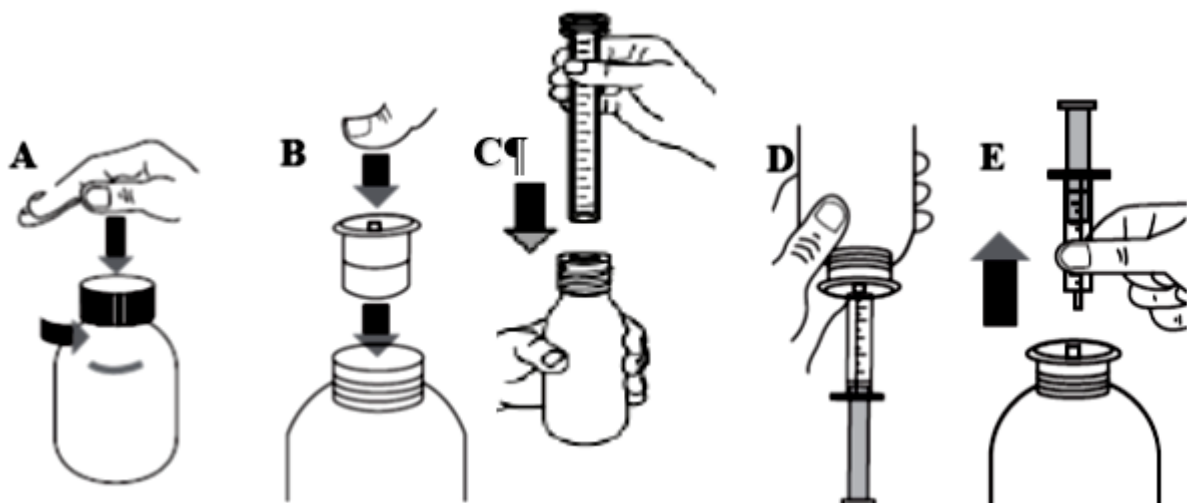
Instructions for dosing:

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is for oral use only.

Incorrect shaking may lead to overdose or underdose of apixaban.

A 10 ml graduated dosing pipette with intermediate graduations of 0.5 ml and a “press-in” dosing pipette/bottle adaptor are provided with the product.

1. Shake the bottle well, before use. It is important to shake the bottle for at least 20 seconds before use.
2. Open the bottle and at first use insert the “Press-In” Bottle Adapter (PIBA) (see pictures A-B).
3. Insert the dosing pipette into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).
4. Remove the filled dosing pipette from the bottle in the upright position (see picture E).
5. Discharge the dosing pipette contents into the mouth.
6. Rinse the dosing pipette and replace the cap on the bottle (PIBA remains in place).



If necessary, your doctor can give you Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik via intragastric feeding tube (nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tube).

Take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik as recommended for the following:

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

The recommended dose is 2.5 ml of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik twice a day. For example, once in the morning and once 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 suspension for 32 to 38 days. If you have had a major **knee** operation, you will usually take the suspension 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.

The recommended dose is 5 ml of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik twice a day.

The recommended dose is 2.5 ml of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 2.5 ml twice a day, for example, once in the morning and once 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 **10 ml** of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik twice a day for the first 7 days, for example, 10 ml in the morning and 10 ml in the evening.

After 7 days the recommended dose is **5 ml** of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik twice a day, for example, 5 ml in the morning and 5 ml in the evening.

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

The recommended dose is **2.5 ml** of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik twice a day for example, 2.5 ml in the morning and 2.5 ml in the evening.

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

Use in children and adolescents

For treating blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of your lungs.

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

Try to take or give the dose at the same times every day to have the best treatment effect.

The dose of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik depends on the body weight and will be calculated by the doctor.

The recommended dose for children and adolescents weighing at least 35 kg is 10 ml of this medicine twice a day for the first 7 days, for example, 10 ml in the morning and 10 ml in the evening.

After 7 days the recommended dose is 5 ml of this medicine. twice a day, for example, 5 ml in the morning and 5 ml in the evening.

For parents or caregivers: please observe the child to ensure that the full dose is taken.

It is important to keep scheduled doctor's visits because the dose may need to be adjusted as the weight changes.

Your doctor might change your anticoagulant treatment as follows:

Changing from Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik to anticoagulant medicines

Stop taking Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next dose of the oral suspension.

Changing from anticoagulant medicines to Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Stop taking the anticoagulant medicines. Start treatment with Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood measurements and instruct you when to start taking Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik.

Changing from Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik.

The child's doctor might change anticoagulant treatment as follows:

- Changing from anticoagulant medicines to Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Stop giving the anticoagulant medicines. Start treatment with Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik at the time the child 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Stop giving the medicine containing a vitamin K antagonist. The child's doctor needs to do blood-measurements and instruct you when to start giving the child Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik.

Patients undergoing cardioversion

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik than you should

Tell your doctor immediately if you have taken more than the prescribed dose of Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik. Take the medicine pack with you, even if there is no suspension left.

If you take more Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik than recommended, you may have an increased risk of bleeding. If bleeding occurs, surgery or blood transfusions or other treatments that may reverse anti factor Xa activity may be required.

If you forget to take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

- If you miss a morning dose, take it as soon as you remember, and it may be taken together with the evening dose.
- A missed evening dose can only be taken during the same evening. Do not take two doses the next morning, instead continue to follow the dosing schedule twice daily as recommended on the next day.

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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Do not stop taking Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is bleeding which may be potentially life threatening and require immediate medical attention.

The following side effects are known if you take Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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
- Itching
- 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)

- 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik to treat or prevent reoccurrence 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 your 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)

Additional side effects in children and adolescents

Tell the child's doctor immediately if you observe any of these symptoms;

- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. The frequency of these side effects is common (may affect up to 1 in 10 people).

In general, the side effects observed in children and adolescents treated with Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik were similar in type to those observed in adults and were primarily mild to moderate in severity. Side effects that were observed more often in children and adolescents were nose bleed and abnormal vaginal bleeding.

Very Common side effects (may affect more than 1 in 10 people)

- Bleeding including:
 - from the vagina;
 - from the nose.

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

- Bleeding including:
 - from the gums;
 - blood in the urine;
 - bruising and swelling;
 - from the bowel or rectum;
 - bright/red blood in the stools;
 - bleeding after an operation including bruising and swelling, blood leaking from the surgical wound/incision (wound secretion) or injection site;
- Hair loss;
- Anaemia which may cause tiredness or paleness;
- Reduced number of platelets in the child's blood (which can affect clotting);
- Nausea (feeling sick);
- Skin rash;
- Itching;
- Low blood pressure which may make the child feel faint or have a quickened heartbeat;
- Blood tests may show:
 - abnormal liver function;
 - an increase in some liver enzymes;
 - an increase in alanine aminotransferase (ALT).

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

- Bleeding:
 - into the abdomen or the space behind the abdominal cavity;
 - in the stomach;
 - in the eyes;
 - in the mouth;
 - from a haemorrhoid;
 - in the mouth or blood in the spit when coughing;
 - in the brain or in the spinal column;
 - in the lungs;
 - into a muscle;
- 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;

- Blood tests may show:
 - an increase in gamma-glutamyltransferase (GGT);
 - tests showing blood in the stools or in the urine.
- 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 national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik contains

- The active substance is apixaban. Each ml of suspension contains 1 mg of apixaban.
- The other ingredients are: citric acid, sodium citrate, glycerol, cherry flavour (1221/21), polysorbate 80, simethicone emulsion, sodium benzoate, sucralose, xanthan gum, citric acid (as solution 30% w/w), purified water.

What Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik looks like and contents of the pack

Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik is an off white to white, slightly viscous suspension with characteristic odour.

The product is available in the following presentation:

Amber glass bottle of 200 ml nominal volume, with plastic screw cap for children safety. Each bottle contains 150 ml of the product. The pack also contains a 10-ml dosing pipette with graduation of 0.5 ml.

Patient Alert Card: handling information

Inside the Apixaban Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik 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 Pharmaplot MFN 1 mg/ml, suspensie voor oraal gebruik. **You should keep this card with you at all times.**

1. Take the card
2. Separate your language as needed (this is facilitated by the perforated edges)
3. Complete the following sections or ask your doctor to do it:

Name:

Birth Date:

Indication:

Weight:

Dose :mg twice daily

Doctor's Name:

Doctor's telephone:

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

Houder van de vergunning voor het in de handel brengen en fabrikanten

Vergunninghouder:

Pharmaplot MFN P.C.

Mouson 40a & Kleisthenous 209

15344 Pallini

Griekenland

Fabrikanten:

Medicair Bioscience Laboratories S.A

Athinon, Lamias National Road 61st km

32009 Schimatari

Griekenland

Pharmaplot P.C.

Kleisthenous and 40a Mouson Str.

15344 Athene

Griekenland

In het register ingeschreven onder:

RVG 133882

Deze bijsluiter is voor het laatst goedgekeurd in januari 2026.