

PACKAGE LEAFLET: INFORMATION FOR USER

PLASIV® 2.5mg Film-Coated Tablets

PLASIV® 5mg Film-Coated Tablets

Apixaban

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).

In this leaflet

1. What PLASIV is and what it is used for.
2. What you need to know before you take PLASIV.
3. How to take PLASIV.
4. Possible side effects.
5. How to store PLASIV.
6. Further information.

1. What PLASIV is and what it is used for

PLASIV contains the active substance Apixaban which 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.

PLASIV 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.
- 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.

PLASIV 2.5 mg only

- 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.

2. What you need to know before you take PLASIV

Do not take PLASIV if you:

- Are allergic to apixaban or any of the other ingredients of this medicine (listed in section 6).
- Are bleeding excessively.
- Have a disease in an organ of the body that increases the risk of serious bleeding (such as an ulcer or a recent ulcer of the stomach or bowel, a recent bleeding in your brain).
- Have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy).
- 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
- Severe kidney disease or if you are on dialysis.
- Liver problem or a history of liver problems (PLASIV 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 PLASIV 5 hours or more after catheter removal.

Take special care with PLASIV

- 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

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

Other medicines and PLASIV

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

The following medicines may increase the effects of PLASIV 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).
- Some 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 PLASIV to help prevent blood clots from forming:

- Medicines to prevent epilepsy or seizures (e.g., Phenylin, 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 PLASIV on pregnancy and the unborn child are not known. You should not take PLASIV if you are pregnant. Contact your doctor immediately if you become pregnant while taking PLASIV.
- It is not known if PLASIV 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/milk start taking PLASIV.

Driving and using machines

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

PLASIV contains lactose (a type of sugar) and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take PLASIV

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

Swallow the tablet with a drink of water. PLASIV 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 PLASIV. 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.

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 PLASIV tablet mixed in 60 mL of water or 5% dextrose in water, through a nasogastric tube.

Take PLASIV as recommended for the following:

- To prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor.

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

The recommended dose is one tablet of PLASIV 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 PLASIV 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 PLASIV 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 PLASIV 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.

PLASIV 2.5 mg only

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

The recommended dose is one tablet of PLASIV 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.

Your doctor might change your anticoagulant treatment as follows:

• Changing from PLASIV to anticoagulant medicines.

Stop taking PLASIV. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.

• Changing from anticoagulant medicines to PLASIV.

Stop taking the anticoagulant medicines. Start treatment with PLASIV 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 PLASIV.

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

• Changing from PLASIV 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 PLASIV for at least 24 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 PLASIV.

Patients undergoing cardioversion

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take PLASIV 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 PLASIV than you should

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

If you take more PLASIV 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 PLASIV

Take the dose as soon as you remember and:

- take the next dose of PLASIV 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 PLASIV

If you stop taking PLASIV without talking to your doctor first, because of the risk of developing a blood clot, you may be at a higher risk 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, PLASIV can cause side effects, although not everybody gets them. PLASIV 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 PLASIV is bleeding which may be potentially life threatening and require immediate medical attention.

The following side effects are known if you take PLASIV 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 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)

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

- Bleeding including:
 - 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 including:
 - 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 PLASIV 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
 - 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)

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 including:
 - 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 including:
 - 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 PLASIV 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.

- 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
 - 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)

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 including:
 - 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 including:

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

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

• Bleeding including:

- Into your abdomen or the space behind your abdominal cavity.

PLASIV 2.5 mg only

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

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

- Anemia 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 including:
 - 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 including:

- 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 including:

- 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

Reporting of side effects

If any of the side effects gets serious, or if you notice any possible side effects not listed in the leaflet, please tell your doctor or pharmacist. You can also report side effects directly (see section 6). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PLASIV

- 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 blister after EXP: The expiry date refers to the last day of that month.
- Do not store above 30°C.
- 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 PLASIV contains

The active substance is Apixaban. Each tablet contains 2.5 mg or 5 mg of Apixaban.

The other ingredients are:

Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Sodium Lauryl Sulfate, Povidone, Magnesium Stearate and Instant universal yellow (PLASIV 2.5 mg) and Instant universal pink (PLASIV 5 mg).

See section 2 "PLASIV" contains lactose (a type of sugar) and sodium".

What PLASIV looks like and contents of the pack

PLASIV 2.5 mg Yellow coloured, round, biconvex, film coated tablets, debossed "F51" on one side and plain on other side.

PLASIV 5 mg Pink coloured, capsule shaped, film coated tablets, debossed "F52" on one side and plain on other side.

PLASIV 2.5 mg and 5 mg contained in blister packs containing 10 tablets and each box contains three or six blisters (30 tablets) or (60 tablets).

Marketing Authorisation Holder and Packing by:

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Manufactured by:

Macleods Pharmaceuticals Limited, Himachal Pradesh, India.

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To report any side effect(s):
Saudi Arabia:
The National Pharmacovigilance (NPC)
SFDA Call Center: 19999
E-mail: npc.drug@sfdagov.sa
Website: https://ade.sfdagov.sa

Other GCC States:
Please contact the relevant competent authority.

THIS IS A MEDICATION

- Medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of reach of children.

Council of Arab Health Ministers
Union of Pharmacists

This patient information leaflet is approved by SFDA



شركة مصنع الأراي للصناعات الدوائية ذ.م.ج.

جدة - المملكة العربية السعودية

ALRAI Pharmaceutical Industries Co. (L.L.C.)
Jeddah-Kingdom of Saudi Arabia

