Package leaflet: Information for the user

Arovi 12,000 IU (120 mg)/0.8 mL solution for injection in pre-filled syringe

enoxaparin sodium

Read all of this leaflet carefully before you start using 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Arovi is and what it is used for

Arovi contains the active substance called enoxaparin sodium that is a low molecular weight heparin (LMWH).
Arovi works in two ways.
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm
2) Stopping blood clots from forming in your blood.

Arovi can be used to:
- Treat blood clots that are in your blood.
- Stop blood clots from forming in your blood in the following situations:
  - Before and after an operation
  - When you have an acute illness and face period of limited mobility
  - If you have experienced a blood clot due to cancer to prevent further clots from forming
  - When you have unstable angina (a condition when not enough blood gets to your heart)
  - After a heart attack
- Stop blood clots forming in the tubes of your dialysis machine (used for people with severe kidney problems).

2. What you need to know before you use Arovi

Do not use Arovi
- If you are allergic to enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are allergic to heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin.

- If you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) - this reaction is called heparin-induced thrombocytopenia - within the last 100 days or if you have antibodies against enoxaparin in your blood.
- If you are bleeding heavily or have a condition with a high risk of bleeding (such as stomach ulcer, recent surgery of the brain or eyes), including recent bleeding stroke.
- If you are using Arovi to treat blood clots in your body and going to receive spinal or epidural anaesthesia or lumbar puncture within 24 hours.

Warnings and precautions
Arovi should not be used interchangeably with other medicines belonging to the group of low molecular weight heparins. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Arovi if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your platelets
- you are going to receive spinal or epidural anesthesia or lumbar puncture (see Operations and Anaesthetics): a delay should be respected between Arovi use and this procedure
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high level of potassium in your blood (this may be checked with a blood test)
- are currently using medicines which affect bleeding (see section below – Other medicines)

You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

Children and adolescents
The safety and efficacy of enoxaparin has not been evaluated in children or adolescents.

Other medicines and Arovi
Tell your doctor or pharmacist if you are taking or might take/use any other medicines.
- Warfarin – used for thinning the blood
- Aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see also in section 3, “Changing of anticoagulant medicine”)
- Dextran injection – used as a blood replacer
- Ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory agents which are used to treat pain and swelling in arthritis and other conditions
- Prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- Medicines which increase potassium level in your blood such as potassium salts, water pills, some medicines for heart problems.

Operations and Anaesthetics
If you are going to have a spinal puncture or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Arovi. See “Do not use Arovi”. Also, tell your doctor if you have any problem with your spine or if you ever had spinal surgery.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

Driving and using machines
Arovi does not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

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

3. How to use Arovi

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

Having this medicine
- Your doctor or nurse will normally give you Arovi. This is because it needs to be given as an injection.
- When you go home, you may need to continue to use Arovi and give it yourself (see instructions below on how to do this).
- Arovi is usually given by injection underneath the skin (subcutaneous).
- Arovi can be given by injection into your vein (intravenous) after certain types of heart attack or operation.
- Arovi can be added to the tube leaving the body (arterial line) at the start of the dialysis session.

Do not inject Arovi into a muscle.

How much will be given to you
- Your doctor will decide how much Arovi to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Arovi.

1. Treating blood clots that are in your blood
    - The usual dose is 150 IU (1.5 mg) for every kilogram of your weight each day or 100 IU (1 mg) for every kilogram of your weight twice a day.
    - Your doctor will decide how long you should receive Arovi.

2. Stopping blood clots forming in your blood in the following situations:
    ❖ *Operation or periods of limited mobility due to an illness*
    - The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Arovi each day.
    - If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
    - If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Arovi each day.
    - Your doctor will decide how long you should receive Arovi.

    ❖ *After you have had a heart attack*

Arovi can be used for two different types of heart attack called STEMI (ST segment elevation myocardial infarction) or Non STEMI (NSTEMI). The amount of Arovi given to you will depend on your age and the kind of heart attack you have had.

NSTEMI type of heart attack:

- The usual dose is 100 IU (1 mg) for every kilogram of weight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Arovi.

STEMI type of heart attack if you are under 75 years old:

- An initial dose of 3,000 IU (30 mg) of Arovi will be given as injection into your vein.
- At the same time you will also be given Arovi as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your weight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Arovi.

STEMI type of heart attack if you are 75 years old or older:

- The usual dose is 75 IU (0.75 mg) for every kilogram of your weight, every 12 hours.
- The maximum amount of Arovi given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Arovi.

For patients that have an operation called percutaneous coronary intervention (PCI):
Depending on when you were last given Arovi, your doctor may decide to give an additional dose of Arovi before a PCI operation. This is by injection into your vein.

3. Stopping blood clots from forming in the tubes of your dialysis machine
    - The usual dose is 100 IU (1 mg) for every kilogram of your weight.
    - Arovi is added to the tube leaving the body (arterial line) at the start of the dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a further dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your weight, if necessary.

Instructions for use of the syringe
How to give yourself an injection of Arovi
If you are able to give Arovi to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called "subcutaneous injection") will help reduce pain and bruising at the injection site.

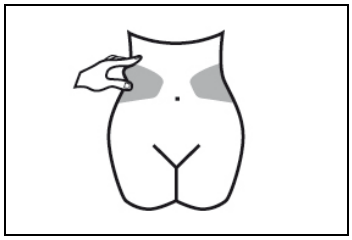
Before injecting yourself with Arovi

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container.
- Check the expiry date on the medicine. Do not use if the date has passed.
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe.
- Make sure you know how much you are going to inject.
- Check your abdomen to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse.

Instructions on injecting yourself with Arovi:
(Instructions for syringes without safety device)

Preparing the injection site
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
    • Do not inject yourself within 5cm of your belly button or around existing scars or bruises.

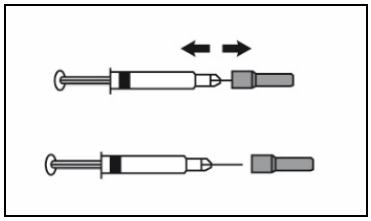
• Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

Selecting your dose

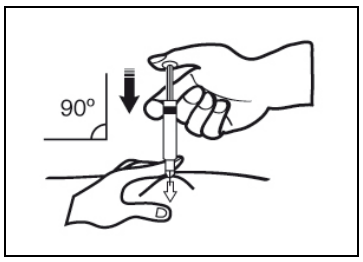
1) Carefully pull off the needle cap from the syringe. Throw away the cap.
   • Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
   • Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



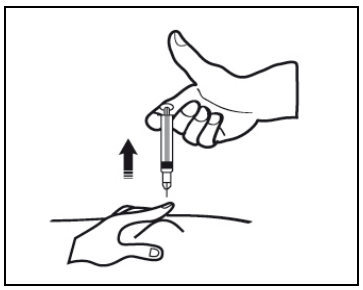
2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

Injecting

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   • Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.



3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. Orient the needle away from the user and anyone else who is present. You can now let go of the skin fold.



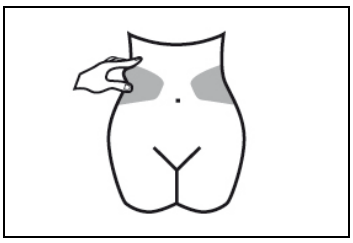
When you have finished
1) To avoid bruising, do not rub the injection site after you have injected yourself.
2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

If you get the impression that the dose is either too strong (for example, you are experiencing unexpected bleeding) or too weak (for example, the dose doesn't seem to be working), talk to your doctor or pharmacist.

Instructions for syringes with safety device:

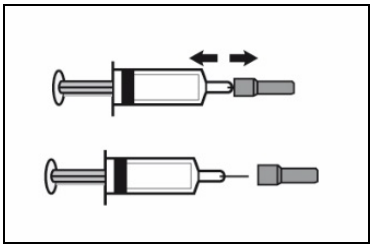
Preparing the injection site
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
   • Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
   • Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

Selecting your dose
1) Carefully pull off the needle cap from the syringe. Throw away the cap.

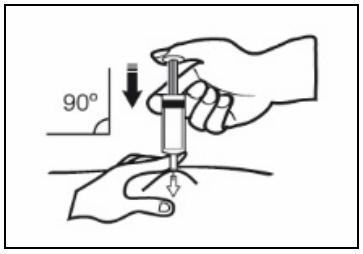
• Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
• Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



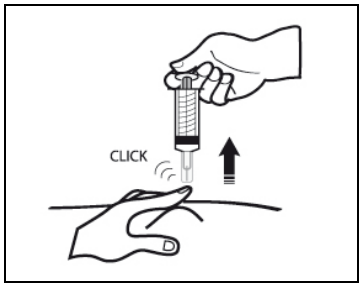
2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

Injecting

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
• Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.



3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out maintaining your finger on the plunger rod. Orient the needle away from the user and anyone else who is present. The safety system is activated by pressing firmly on the plunger rod. The protective sleeve will automatically cover the needle and will produce an audible “click” which confirms the activation of the device. You can now let go of the skin fold.



When you have finished

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

If you get the impression that the dose is either too strong (for example, you are experiencing unexpected bleeding) or too weak (for example, the dose doesn't seem to be working), talk to your doctor or pharmacist.

Changing of anticoagulant treatment

- *Changing from Arovi to blood thinners called vitamin-K antagonists (e.g. warfarin)*
  Your doctor will request you perform blood tests called INR and tell you when to stop Arovi accordingly.

- *Changing from blood thinners called vitamin-K antagonists (e.g. warfarin) to Arovi*
  Stop taking the vitamin-K antagonist. Your doctor will request you perform blood tests called INR and tell you when to start Arovi accordingly.

- *Changing from Arovi to treatment with direct oral anticoagulant*
  Stop taking Arovi. Start taking the direct oral anticoagulant 0-2 hours before the time you would have had the next injection, then continue as normal.

- *Changing from treatment with direct oral anticoagulant to Arovi*
  Stop taking direct oral anticoagulant. Do not start treatment with Arovi until 12 hours after the final dose of direct oral anticoagulant.

If you use more Arovi than you should

If you think that you have used too much or too little Arovi, tell your doctor, nurse or pharmacist immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Arovi, take them to a hospital casualty department straight away.

If you forget to use Arovi

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

If you stop using Arovi

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.
It is important for you to keep having Arovi injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like other similar medicines (medicines to reduce blood clotting), Arovi may cause bleeding which may potentially be life-threatening. In some cases the bleeding may not be obvious.

If you experience any bleeding event that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling), consult your doctor immediately.
Your doctor may decide to keep you under closer observation or change your medicine.

Stop using enoxaparin and seek medical attention immediately if you notice any of the following symptoms:

- Any signs of a severe allergic reaction (such as difficulty breathing, swelling of the lips, mouth, throat or eyes).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

You should tell your doctor straight away

- If you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- If you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.

Overall list of possible side effects:

Very common (may affect more than 1 in 10 people)

- Bleeding.
- Increases in liver enzymes.

Common (may affect up to 1 in 10 people)

- You bruise more easily than usual. This could be because of a blood problem with low platelet counts.
- Pink patches on your skin. These are more likely to appear in the area you have been injected with Arovi.
- Skin rash (hives, urticaria).
- Itchy red skin.
- Bruising or pain at the injection site.
- Decreased red blood cell count.
- High platelet counts in the blood.
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Sudden severe headache. This could be a sign of bleeding in the brain.
- A feeling of tenderness and swelling in your stomach. You may have bleeding in your stomach.
- Large red irregularly shaped skin lesions with or without blisters.
- Skin irritation (local irritation).
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. This could be a liver problem.

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

- Severe allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Increased potassium in your blood. This is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test.
- An increase in the number of eosinophils in your blood. Your doctor will be able to check this by carrying out a blood test.
- Hair loss.
- Osteoporosis (a condition where your bones are more likely to break) after long term use.
- Tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic.
- Loss of control over your bladder or bowel (so you cannot control when you go to the toilet).
- Hard mass or lump at the injection site.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme on website: 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 Arovi

Store below 25°C. Do not freeze.
Arovi prefilled syringes are single dose containers – discard any unused product.

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 label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice the syringe is damaged or the product is not clear.

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 Arovi contains

- The active substance is enoxaparin sodium.

Each pre-filled syringe contains enoxaparin sodium 12,000 IU anti-Xa activity (equivalent to 120 mg) in 0.8 mL water for injections.

- The other ingredient is water for injections.

What Arovi looks like and contents of the pack
Arovi is a clear, colourless to pale yelow solution for injection in a Type I glass pre-filled syringe fitted with an injection needle and with or without an automatic safety device. It is supplied as follows:

Arovi 12,000 IU (120 mg)/0.8 mL solution for injection in a 1 mL graduated pre-filled syringe.
Packs of 10, 30 and 50 syringes.

Not all pack sizes may be marketed.

In some package sizes, the prefilled syringe may be combined to a safety device system.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Laboratorios Farmacéuticos ROVI, S.A.
Julián Camarillo, 35
28037 - Madrid Spain

Manufacturer
ROVI Pharma Industrial Services, S.A.
Julián Camarillo, 35
28037 - Madrid Spain

Distributor in UK (Great Britain):

Rovi Biotech Limited
One Elmfield Park, Office No. 2.06
Bromley BR1 1LU.
United Kingdom

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Germany: **Enoxaparin Becat**

Belgium: **Enoxaparine Becat**

Spain: **Enoxaparina Rovi**

Poland: **Losmina**

United Kingdom (Northern Ireland): **Arovi**

This medicinee is authorised in the United Kingdom (Great Britain) under the name Arovi.

This leaflet was last revised in October 2025.

Other sources of information
Detailed information on this medicine is available on the website of MHRA (https://www.gov.uk)