

# What is AROVI<sup>®</sup> and what is it used for?

## USER INFORMATION GUIDE

▼ This medicinal product is subject to additional monitoring. You can help by reporting any side effects that you may get.

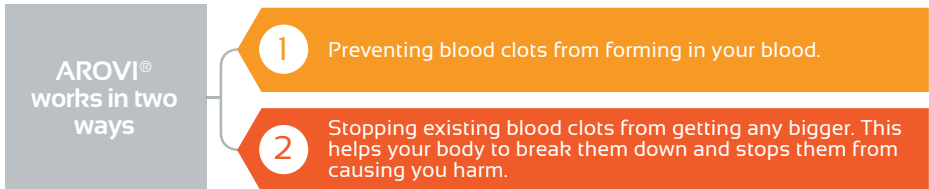
See the back of this booklet for how to report side effects.

This guide intends to further complement information contained in the patient information leaflet (PIL) for patients who have been prescribed AROVI<sup>®</sup>.

Read the contents of the PIL as this guide is not intended as a substitute for the PIL.

## What is AROVI®?

AROVI® contains the active substance called **enoxaparin sodium** that is a low molecular weight heparin (LMWH).



### 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.
  - 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).

AROVI® is available in a range of strengths:

The colour of the box vary depending on the dose that your doctor or nurse has given you. Your doctor decides your dosage based on your needs and current medical conditions.



- AROVI® 2,000 IU (20 mg)/0.2mL
- AROVI® 4,000 IU (40 mg)/0.4mL
- AROVI® 6,000 IU (60 mg)/0.6mL
- AROVI® 8,000 IU (80 mg)/0.8mL
- AROVI® 10,000 IU (100 mg)/1mL
- AROVI® 12,000 IU (120 mg)/0.8mL
- AROVI® 15,000 IU (150 mg)/1mL

## 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: 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.

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.

## What you need to know BEFORE you use AROVI®

### Do NOT use AROVI®



If you are **allergic to enoxaparin sodium**. 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.

## 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.

Your doctor will decide how much AROVI® to administer you. The dose depends on your medical needs.

### Having this medicine:

- Your doctor or nurse will normally administer your AROVI® in the hospital. This is because it needs to be given as an injection.
- When you go home, you may need to continue to use AROVI® and inject it yourself (see instructions on the page on how to do this).
- AROVI® is usually administered by injection underneath the skin (subcutaneous).
- Do not inject AROVI® into a muscle.

## What does AROVI® look like?

AROVI® is a clear, colourless to pale yellow solution in a pre-filled syringe fitted with an injection needle with a safety device.

The pre-filled syringes are stored in plastic trays and carton boxes.

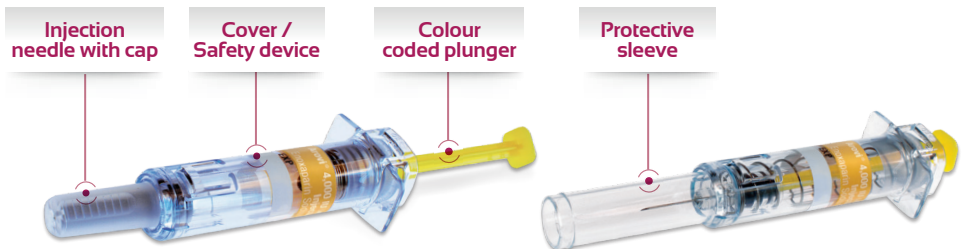


Fig. 1. AROVI® pre-filled syringe **BEFORE** it is injected

Fig. 2. AROVI® pre-filled syringe with the activated protective sleeve **AFTER** it is injected

The colour of the box, the plunger and the label vary depending on the dose that your doctor or nurse has given you. Your doctor decides your dosage based on your needs and current medical conditions.

## How should I inject 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.



AROVI®  
Administration  
VIDEO

To watch this video scan the QR code

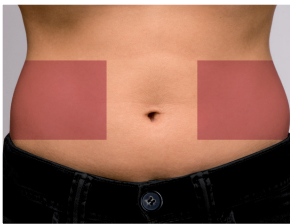
Follow  
these steps

### BEFORE the injection



1

First wash your hands with soap and water and dry them carefully.



2

Sit or lie in a comfortable position so you are relaxed. Choose an area on the right or left side of your stomach. This should be at least 5 cm away from your belly button and out towards your sides. Do not inject yourself within 5 cm 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



3

Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.



AROVI® pre-filled syringe is now ready to be used

## How to inject



4

Remove the syringe from the individual packaging and remove the cap by pulling firmly. The air must not be removed from the syringe. If a drop appears at the end of the needle, it should be removed by shaking. Do not wipe the needle to keep it sterile until use.



5

Make a skin fold in the abdominal area with forefinger and thumb. The skin fold must be maintained during the injection.



6

The entire length of the needle should be inserted **PERPENDICULAR TO THE SKIN** (i.e. with a 90 degree angle) into the skin fold. Slowly inject the contents by pushing the plunger towards the cylinder and holding the skin fold until the needle is removed at the end of the injection.



7

Remove the syringe while keeping your thumb on the plunger. To prevent bruising, do not rub or scratch the puncture site after injection.



8

Once the syringe has been removed from the skin fold, press firmly on the plunger to activate the safety system. The protective cover encloses the needle with an audible **CLICK** that confirms the activation of the safety system.

Immediately, the syringe must be discarded by dropping it into the nearest sharps bin. The container lid must be closed tightly and kept out of the reach of children.

**To prevent bruising DO NOT rub the injection site after administration.**

## 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

**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**



## How do I store AROVI®?



Keep this medicine out of the sight and reach of children



AROV I® prefilled syringes are single dose containers, discard any unused product



Store at room temperature (store below 25°C)



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 freeze or put in the fridge



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

**Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose the no longer required medicines. These measures will help protect the environment.**

### What if....

**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 administer yourself a dose, do it as soon as you remember. Do not administer yourself a double dose on the same day to make up for a forgotten one. 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, pharmacist or nurse. It is important for you to keep administering AROVI® injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

**If you suffer a possible side-effect**

Like other similar medicines (medicines to reduce blood clotting), AROVI® can have side effects. If you suffer any symptoms listed on the following page, **contact your local A&E department, doctor, pharmacist or nurse immediately**. Your doctor may decide to keep you under closer observation or change your medicine.

## Possible side effects

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

- Bleeding.
- Increases in liver enzymes.

### ► Common

- 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.
- 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

- 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

- 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 suffer any side effect, talk to your doctor, pharmacist or nurse or call the NHS. This includes any side effect not listed in the patient information leaflet.

You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>.

Adverse events should also be reported to ROVI Biotech Ltd. on + 44 (0) 203 642 06 77 or [uk-pharmacovigilance@rovi.com](mailto:uk-pharmacovigilance@rovi.com).

By reporting side effects, you can help provide more information on the safety of this medicine.



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