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60 mm

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FPO

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fondaparinux sodium 5 mg/0.4 ml Solution for Injection in Pre-Filled Syringe
Fondaparinux sodium 7.5 mg/0.6 ml Solution for Injection in Pre-Filled Syringe
Fondaparinux sodium 10 mg/0.8 ml Solution for Injection in Pre-Filled Syringe

fondaparinux 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fondaparinux sodium is and what it is used for

Fondaparinux sodium is a medicine that helps prevent blood clots from forming in the blood vessels (*an antithrombotic agent*).

Fondaparinux sodium solution contains a synthetic substance called fondaparinux sodium. This stops a clotting factor Xa ("ten-A") from working in the blood, and so prevents unwanted blood clots *(thromboses)* from forming in the blood vessels.

Fondaparinux sodium is used to treat adults with a blood clot in the blood vessels of their legs (*deep vein thrombosis*) **and/or lungs** (*pulmonary embolism*).

2. What you need to know before you use Fondaparinux sodium

Do not use Fondaparinux sodium:
- **if you are allergic** to fondaparinux sodium or to any of the other ingredients of this medicine listed in section 6
- **if you are bleeding excessively**
- **if you have a bacterial heart infection**
- **if you have very severe kidney disease.**

Tell your doctor if you think any of these apply to you. If they do, you must **not** use Fondaparinux.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Fondaparinux sodium:
- if you have previously had complications during treatment with heparin or heparin-like medicines causing a fall in the number of blood platelets (heparin-induced thrombocytopenia)
- **if you have a risk of uncontrolled bleeding** (haemorrhage) including:
  - **stomach ulcer**
  - **bleeding disorders**
  - recent **bleeding into the brain** (*intracranial bleeding*)
  - **recent surgery** on the brain, spine or eye
- **if you have severe liver disease**
- **if you have kidney disease**
- **if you are 75 years old or older**
- **if you weigh less than 50 kg.**

Tell your doctor if any of these apply to you.

Children and adolescents
Fondaparinux has not been tested in children and adolescents under the age of 17 years.

Other medicines and Fondaparinux sodium
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Some other medicines may affect the way that Fondaparinux sodium works or be affected by Fondaparinux sodium.

Pregnancy and breastfeeding
Fondaparinux sodium should not be prescribed to pregnant women unless clearly necessary. Breastfeeding is not recommended during treatment with Fondaparinux sodium. If you are **pregnant,** or **breastfeeding**, think you may be pregnant, or are planning to have a baby, **ask your doctor or pharmacist for advice before using this medicine.**

Fondaparinux contains sodium
This medicinal product contains less than 23 mg of sodium in each dose and therefore is essentially sodium-free.

3. How to use Fondaparinux sodium

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

Your weight	Usual dose
Below 50 kg	5 mg once a day
Between 50 kg and 100 kg	7.5 mg once a day
Over 100 kg	10 mg once a day. This dose may be reduced to 7.5 mg once a day if you have moderate kidney disease.

You should inject at about the same time each day.

How Fondaparinux sodium is given
- Fondaparinux sodium is given by injection under the skin (*subcutaneously*) into a skin fold of the lower abdominal area. The syringes are pre-filled with the exact dose you need. There are different syringes for the 2.5 mg and 1.5 mg doses. **For step-by-step instructions please see over the page.**
- Do **not** inject Fondaparinux sodium into muscle.

How long should Fondaparinux sodium be taken for
You should continue Fondaparinux sodium treatment for as long as your doctor has told you, since Fondaparinux sodium prevents development of a serious condition.

If you use more Fondaparinux sodium than you should
Contact your doctor or pharmacist for advice as soon as possible, because of the increased risk of bleeding.

If you forget to use Fondaparinux sodium
- **Take the dose as soon as you remember. Do not inject a double dose to make up for a forgotten dose.**
- **If you are not sure what to do,** ask your doctor or pharmacist.

Don't stop using Fondaparinux sodium
If you stop the treatment before your doctor told you to, you are at risk of developing a blood clot in a vein of your leg or lung. **Contact your doctor or pharmacist before stopping.**

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.

Severe allergic reactions (anaphylaxis): These are very rare in people (up to 1 in 10,000) taking Fondaparinux sodium. Signs include:
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in swallowing or breathing
- collapse

Contact a doctor immediately if you get these symptoms. **Stop taking Fondaparinux sodium.**

Common side effects
These may affect **more than 1 in 100 people** treated with Fondaparinux sodium.
- **bleeding** (for example from an operation site, an existing stomach ulcer, nosebleed, gums)

Uncommon side effects
These may affect **up to 1 in 100 people** treated with Fondaparinux sodium.
- swelling (oedema)
- headache
- pain
- feeling sick or being sick (nausea or vomiting)
- low number of red blood cells (anaemia)
- low number of platelets (blood cells necessary for blood clotting)
- increase in some chemicals (enzymes) produced by the liver

Rare side effects
These may affect **up to 1 in every 1000 people** treated with Fondaparinux sodium.
- allergic reaction (including itching, swelling, rash)
- internal bleeding in the brain, liver or abdomen
- rash
- dizziness
- pain and swelling at injection site
- high number of platelets (blood cells necessary for blood clotting)
- increase in the amount of non-protein nitrogen in the blood
- stomach pain
- itching
- indigestion
- diarrhoea or constipation

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

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.

Do not use Fondaparinux sodium:
- after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month
- if you notice any particles in the solution, or if the solution is discoloured
- if you notice that the syringe is damaged
- if you have opened a syringe and you do not use it straightaway.

Disposal of syringes:
Do not throw away any medicines and syringes 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 Fondaparinux sodium contains
- 5 mg fondaparinux sodium in 0.4 ml solution for injection
- 7.5 mg fondaparinux sodium in 0.6 ml solution for injection
- 10 mg fondaparinux sodium in 0.8 ml solution for injection

The other ingredients are sodium chloride, water for injections, and hydrochloric acid and/or sodium hydroxide to adjust the pH.

What Fondaparinux sodium looks like and contents of the pack
Fondaparinux sodium is a clear and colourless to slightly yellow solution for injection. It is supplied in a pre-filled syringe. It is available in packs of 2, 7, 10, 20 and 30 pre-filled syringes (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer
Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD, United Kingdom

This leaflet was last revised in 10/2018

Artwork	
Brand:	Dr Reddy's
Product Name:	Fondaparinux Sodium
Strength	5, 7.5, 10 mg
Form:	Solution for Injection
Component:	Lelafet
Pack Size:	10 syringes
Country:	Leaflet
Date Created:	17/01/2019
Date Modified:	00/00/2018
Version:	1.0

Technical Information

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Dr.Reddy's
Good Health Can't Wait

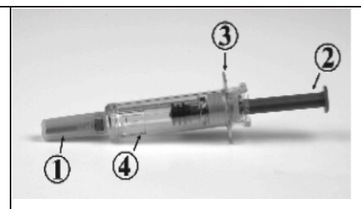
Dr. Reddy's Laboratories (UK) Ltd
6 Riverview Road, Beverley, HU17 0LD, UK

STEP BY STEP GUIDE TO USING FONDAPARINUX SODIUM

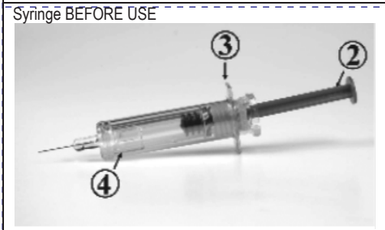
Instructions for self-administration

The different parts of Fondaparinux sodium safety syringe are:

1. Rigid Needle Shield
2. Plunger
3. Finger-grip
4. Safety shield



Syringe BEFORE USE



Syringe AFTER USE

1. Wash your hands thoroughly with soap and water. Towel dry.
2. Sit or lie down in a comfortable position. Choose a spot on the lower stomach area (abdomen), at least 2 inches below your belly button (Figure A). Change (alternate) between using the left and right side of the lower abdomen for each injection. If you have any questions talk to your nurse or doctor.

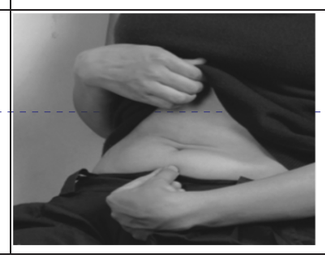


Figure A.

3. Clean the injection area with an alcohol swab.

4. Remove the needle shield by pulling it straight off the syringe (Figure B). Discard the needle shield.
   To prevent infection, do not touch the needle or let it come in contact with any surface before the injection. A small air bubble in the syringe is normal. To be sure that you do not lose any medicine from the syringe, do not try to remove air bubbles from the syringe before giving the injection.

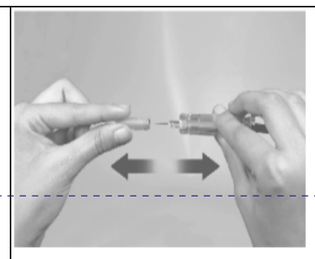


Figure B.

5. Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger of one hand during the entire injection (Figure C).

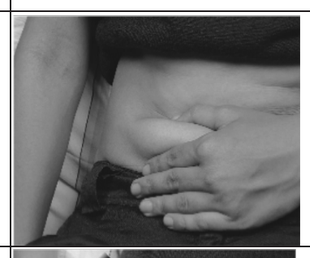


Figure C.

6. Hold the syringe firmly in your other hand using the finger-grip. Insert the full length of the needle directly up and down (at an angle of 90°) into the skin fold (Figure D).

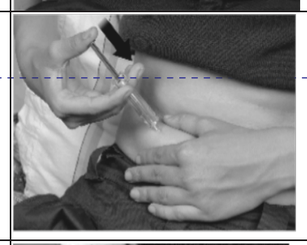


Figure D.

7. Inject all of the medicine in the syringe by pressing down on the plunger as far as it goes. (Figure E).

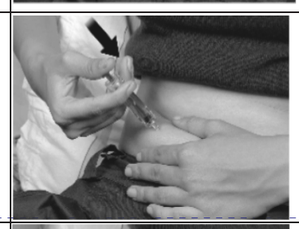


Figure E.

8. Remove the syringe from the injection site keeping your finger on the plunger.

Figure F.

9. Orient the needle away from you and others, and activate the safety shield by firmly pushing the plunger. The protective sleeve will automatically cover the needle and an audible "click" will be heard to confirm shield activation.

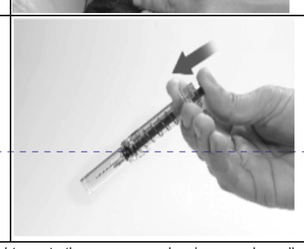


Figure G.

Follow the instructions given to you by your nurse or doctor about the right way to throw away used syringes and needles. There may be state laws about the right way to dispose of used syringes, needles, and disposal containers.

NOTE:

- The safety system can only be activated once the syringe has been emptied.
- Activation of the safety system must be done only after removing the needle from the patient's skin.
- Do not replace the needle shield after injection.
- The safety system should not be sterilized.
- Activation of the safety system may cause minimal splatter of fluid. For optimal safety activate the system while orienting it downwards away from yourself and others.