

PACKAGE LEAFLET

Package leaflet: Information for the user
Fondaparinux Sodium Aspen 2.5 mg/0.5 ml solution for injection, 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 or pharmacist.
- 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 Fondaparinux Sodium Aspen is and what it is used for
2. What you need to know before you use Fondaparinux Sodium Aspen
3. How to use Fondaparinux Sodium Aspen
4. Possible side effects
5. How to store Fondaparinux Sodium Aspen
6. Contents of the pack and other information

1. What Fondaparinux Sodium Aspen is and what it is used for

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

Fondaparinux Sodium Aspen 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 Aspen is used to:

- prevent the formation of blood clots in the blood vessels of the legs or lungs after orthopaedic surgery (such as hip or knee surgery) or abdominal surgery
- prevent the formation of blood clots during and shortly after a period of restricted mobility due to acute illness
- treat some types of heart attack and severe angina (pain caused by narrowing of the arteries in the heart)
- treat blood clots in blood vessels that are near the surface of the skin of the legs (*superficial-vein thrombosis*)

2. What you need to know before you use Fondaparinux Sodium Aspen

Do not use Fondaparinux Sodium Aspen:

- **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 applies to you. If they do, you must **not** use Fondaparinux Sodium Aspen.

Take special care with Fondaparinux Sodium Aspen:

Talk to your doctor or pharmacist before taking Fondaparinux Sodium Aspen:

- 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 applies to you.

Children and adolescents

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

Other medicines and Fondaparinux Sodium Aspen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you bought without a prescription. Some other medicines may affect the way that Fondaparinux Sodium Aspen works or be affected by Fondaparinux Sodium Aspen.

Pregnancy and breast-feeding

Fondaparinux Sodium Aspen should not be prescribed to pregnant women unless clearly necessary. Breast-feeding is not recommended during treatment with Fondaparinux Sodium Aspen. If you are **pregnant**, or **breast-feeding**, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fondaparinux Sodium Aspen contains sodium

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

Fondaparinux Sodium Aspen syringe contains latex

The syringe needle shield contains latex that may cause severe allergic reactions.

➔ **Tell your doctor** if you are allergic to latex before being treated with Fondaparinux Sodium Aspen.

3. How to use Fondaparinux Sodium Aspen

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

The recommended dose is 2.5 mg once a day, injected at about the same time each day.

If you have kidney disease, the dose may be reduced to 1.5 mg once a day.

How Fondaparinux Sodium Aspen is given

- Fondaparinux Sodium Aspen 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.** To treat some types of heart attack, a health professional may give the first dose into a vein (*intravenously*)
- Do **not** inject Fondaparinux Sodium Aspen into muscle.

How long should Fondaparinux Sodium Aspen be taken for

You should continue Fondaparinux Sodium Aspen treatment for as long as your doctor has told you, since Fondaparinux Sodium Aspen prevents development of a serious condition.

If you inject too much Fondaparinux Sodium Aspen

Contact your doctor or pharmacist for advice as soon as possible because of the increased risk of bleeding.

If you forget to take Fondaparinux Sodium Aspen

- 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 Aspen without advice

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 or pharmacist.

4. Possible side effects

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

Conditions you need to look out for

Severe allergic reactions (anaphylaxis): These are very rare in people (up to 1 in 10,000) taking Fondaparinux Sodium Aspen. 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 Aspen.**

Common side effects

These may **affect more than 1 in 100 people** treated with Fondaparinux Sodium Aspen.

- **bleeding** (for example from an operation site, an existing stomach ulcer, nosebleed, gums)
- **anaemia** (a reduction in the number of red blood cells)

Uncommon side effects

These may affect **up to 1 in 100 people** treated with Fondaparinux Sodium Aspen.

- bruising or swelling (*oedema*)
- feeling sick or being sick (*nausea* or *vomiting*)
- chest pain
- breathlessness
- rash or itchy skin
- oozing from operation wound site
- fever
- reduction or increase in the 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 Aspen.

- allergic reaction (including itching, swelling, rash)
- internal bleeding in the brain or abdomen
- anxiety or confusion
- headache
- fainting or dizziness, low blood pressure
- drowsiness or tiredness
- flushing
- coughing
- leg pain or stomach pain
- diarrhoea or constipation
- indigestion
- wound infection
- increase in bilirubin (a substance produced by the liver) in the blood
- reduction in potassium in your blood

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRC Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fondaparinux Sodium Aspen

- Keep this medicine out of the sight and reach of children
- Store below 25°C. Do not freeze
- Fondaparinux Sodium Aspen does not need to be kept in the fridge.

Do not use this medicine:

- after the expiry date shown on the label and carton
- 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 or syringes via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. Contents of the pack and other information

What Fondaparinux Sodium Aspen contains

- The active substance is 2.5 mg fondaparinux sodium in 0.5 ml solution for injection
- The other ingredient(s) are sodium chloride, water for injections, and hydrochloric acid and/or sodium hydroxide to adjust the pH (see section 2)

Fondaparinux Sodium Aspen does not contain any animal products.

What Fondaparinux Sodium Aspen looks like and contents of the pack

Fondaparinux Sodium Aspen is a clear and colourless solution for injection. It is supplied in a pre-filled, single-use syringe fitted with a safety system to help prevent needle stick injuries after use. It is available in packs of 2, 7, 10 and 20 pre-filled syringes (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

Manufacturer:

Aspen Notre Dame de Bondeville, 1 rue de l'Abbaye, F-76960 Notre Dame de Bondeville, France.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland: Fondaparinux Sodium Aspen 2.5 mg/0.5 ml solution for injection, pre-filled syringe

France: Fondaparinux Sodique Aspen 2,5mg/0,5mL solution injectable en seringue pré-remplie

This leaflet was last revised in

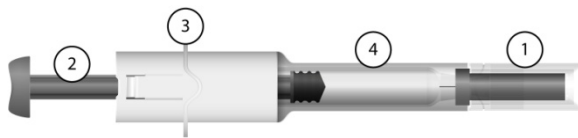
Types of safety syringe

There are two types of safety syringes used for Fondaparinux Sodium Aspen, designed to protect you from needle stick injuries following injection. One type of syringe has an **automatic** needle protection system and the other type has a **manual** needle protection system.

Parts of the syringes:

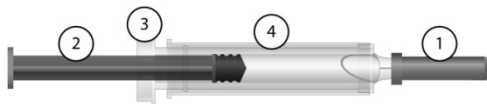
- ① Needle shield
- ② Plunger
- ③ Finger-grip
- ④ Security sleeve

Picture 1. Syringe with an **automatic** needle protection system

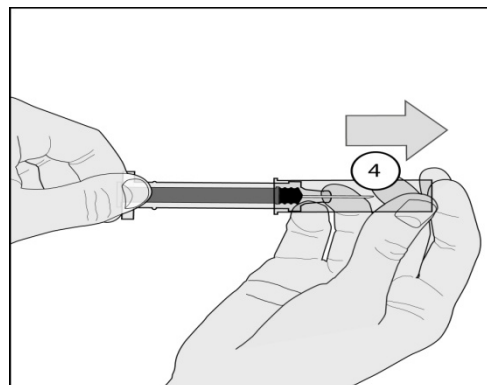


Syringe with a **manual** needle protection system

Picture 2. Syringe with a **manual** needle protection system



Picture 3. Syringe with a **manual** needle protection system showing security sleeve being pulled over needle **AFTER USE**



STEP BY STEP GUIDE TO USING FONDAPARINUX SODIUM ASPEN

Instructions for use

These instructions are for both types of syringes (automatic and manual needle protection system). Where the instruction for a syringe is different this is clearly stated.

1. Wash your hands thoroughly with soap and water and dry them with a towel.

2. Remove the syringe from the carton and check that:

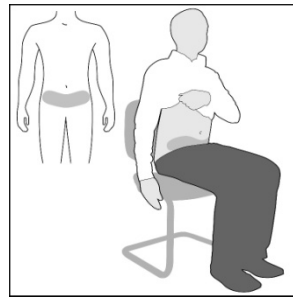
- the expiry date has not passed
- the solution is clear and colourless and doesn't contain particles
- the syringe has not been opened or damaged

3. Sit or lie down in a comfortable position.

Choose a place in the lower abdominal (tummy) area, at least 5 cm below your belly button (picture A).

Alternate the left and right side of the lower abdominal area at each injection. This will help to reduce the discomfort at the injection site.

If injecting in the lower abdominal area is not possible, ask your nurse or doctor for advice.



Picture A

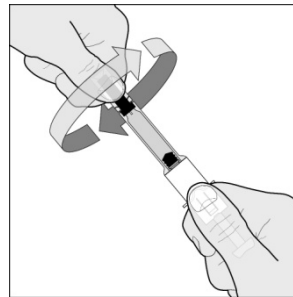
4. Clean the injection area with an alcohol wipe.

5. Remove the needle shield, by first twisting it (picture B1) and then pulling it in a straight line away from the body of the syringe (picture B2).

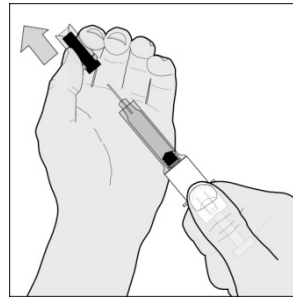
Discard the needle shield.

Important note

- **Do not touch the needle** or allow it to touch any surface before the injection.
- It is normal to see a small air bubble in this syringe. **Do not try to remove this air bubble before making the injection** - you may lose some of the medicine if you do.

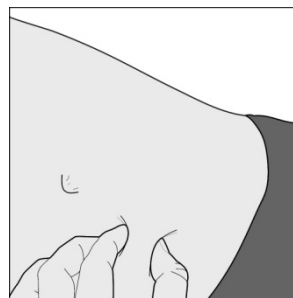


Picture B1



Picture B2

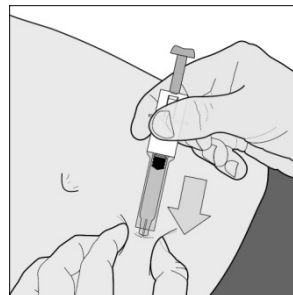
6. Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger during the entire injection (picture C).



Picture C

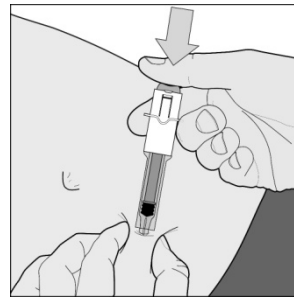
7. Hold the syringe firmly by the finger grip.

Insert the full length of the needle at right angles into the skin fold (picture D).



Picture D

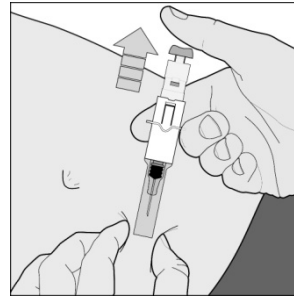
8. Inject ALL of the contents of the syringe by pressing down on the plunger as far as it goes (picture E).



Picture E

Syringe automatic system

9. Release the plunger and the needle will automatically withdraw from the skin and go back into the security sleeve where it will be locked permanently (picture F).



Picture F

Syringe manual system

9. After the injection hold the syringe in one hand by gripping the security sleeve, use the other hand to hold the finger grip and pull firmly back. This unlocks the sleeve. Slide the sleeve up the body of the syringe until it locks into position over the needle. This is shown in Picture 3 at the beginning of these instructions.

Do not dispose of the used syringe in the household waste. Dispose of it as your doctor or pharmacist has instructed.