Package leaflet: Information for the user

arixtra®
5 mg/0.4 ml
7.5 mg/0.6 ml
10 mg/0.8 ml
solution for injection
fondaparinux sodium

arixtra®

5 mg/0.4 ml
7.5 mg/0.6 ml
10 mg/0.8 ml

solution for injection
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 Arixtra is and what it is used for

Arixtra is a medicine that treats or helps to prevent blood clots from forming in the blood vessels (*an antithrombotic agent*).

Arixtra 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.

Arixtra 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 Arixtra

Do not use Arixtra:
- **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 severe kidney disease**.

➜ **Tell your doctor** if you think any of these applies to you. If they do, you must **not** use Arixtra.

Take special care with Arixtra:
Talk to your doctor or pharmacist before taking Arixtra:
- **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.**

➜ **Tell your doctor** if any of these applies to you.

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

Other medicines and Arixtra
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 Arixtra works or be affected by Arixtra.

Pregnancy and breast-feeding
Arixtra should not be prescribed to pregnant women unless clearly necessary. Breast-feeding is not recommended during treatment with Arixtra. 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.

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

Arixtra syringe contains latex
The syringe needle shield contains latex that has the potential to cause allergic reactions in latex sensitive individuals.

➜ **Tell your doctor** if you are allergic to latex before being treated with Arixtra.

3 How to use Arixtra

Always use this medicine exactly as your doctor or pharmacist 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 Arixtra is given
- Arixtra 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 5 mg, 7.5 mg and 10 mg doses. **For step-by-step instructions please see over the page**.
- Do **not** inject Arixtra into muscle.

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

If you inject too much Arixtra
Contact your doctor or pharmacist for advice as soon as possible, because of the increased risk of bleeding.

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

Don't stop using Arixtra without advice
If you stop the treatment before your doctor told you to, the blood clot may not be treated properly and you may also be at risk of developing a new blood clot in a vein of your leg or in the 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 Arixtra. 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 Arixtra**.

Common side effects
These may affect **more than 1 in 100 people** treated with Arixtra.
- **bleeding** (for example from an operation site, an existing stomach ulcer, nosebleed, bruising gums, blood in urine, coughing up blood, bleeding from eyes, bleeding in joint spaces, internal bleeding in uterus)
- **localised collection of blood** (in any organ/body tissue)
- **anaemia** (a reduction in the number of red blood cells)
- **bruising**.

Uncommon side effects
These may affect **up to 1 in 100 people** treated with Arixtra.
- swelling (*oedema*)
- headache
- pain
- chest pain
- breathlessness
- rash or itchy skin
- oozing from operation wound site
- fever
- feeling sick or being sick (*nausea or vomiting*)
- reduction or increase in the number of platelets (blood cells necessary for blood clotting)
- increase in some chemical (*enzymes*) produced by the liver

Rare side effects
These may affect **up to 1 in every 1000 people** treated with Arixtra.
- allergic reaction (including itching, swelling, rash)
- internal bleeding in the brain, liver or abdomen
- anxiety or confusion
- fainting or dizziness, low blood pressure
- drowsiness or tiredness
- flushing
- coughing
- pain and swelling at injection site
- wound infection
- increase in the amount of non-protein nitrogen in the blood
- leg or stomach pain
- indigestion
- diarrhoea or constipation
- increase in bilirubin (a substance produced by the liver) in the blood
- reduction in potassium in your blood
- pain around the upper part of the stomach or heartburn.

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 Yellow Card Scheme at 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 Arixtra

- Keep this medicine out of the sight and reach of children
- Store below 25°C. Do not freeze
- Arixtra does not have 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 Arixtra contains
The active substance is:
- 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 ingredient(s) are sodium chloride, water for injections, and hydrochloric acid and/or sodium hydroxide to adjust the pH (see section 2).

Arixtra does not contain any animal products.

What Arixtra looks like and contents of the pack
Arixtra is a clear and colourless to slightly yellow solution for injection. It is supplied in a pre-filled 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).

➜

VIATRIS			
Description	arixtra, 10 mg/0.8 ml, 11 mg/0.8 ml, 6 mg/0.4 ml, 7.5 mg/0.6 ml, 5 mg/0.4 ml, 10	Date: 23 NOV 2023	Time: 17:00
Component Type	Leaflet/IFU - Folded	Site Barcode/ DataMatrix: TBC	No. of colours: 3 / Page Count: 1 of 2
Affiliate Item Code	ART-5428-02	Viatris SAP No.: 400557889, 400557887, 400557890	Colours: Black, Magenta, Cyan
Superseded Affiliate Item Code	322802	Vendor Job No.: N.A.	Non-Print Colours: Keyline
TrackWise/GLAMS Job No.	ART-5428-02	Artwork Proof No.: 1	Equate CMYK with:
MA No.	PLGB 46302/0232, PLGB 46302/0233, PLGB 46302/0229	Client Market: United Kingdom	Main Font: Frutiger Next / Body Text Size: 8 pt
Supplier SAP No.	N.A.	Barcode Info: N.A.	Dimensions: 480x200 mm / Min Text Size used: 8 pt
New Supplier Code	TBC	3D Render ID: N.A.	Keyline/Drawing No.: NB-NOT-011-E-FM_ASPEN_01_LAYOUT1
Superseded Supplier Code	TBC		
Packing Site/Printer	Aspen NDB SAS (Notre-Dame-de-Bondeville - FR)		
Sign-offs			V3 MAY 2023

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Mylan Products Ltd. 20 Station Close, Potters Bar, Herts, EN6 1TL, United Kingdom

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

This leaflet was last revised in November 2023

Mylan

ART-5428-02

STEP BY STEP GUIDE TO USING ARIXTRA

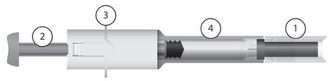
Types of safety syringe

There are two types of safety syringes used for Arixtra, 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:

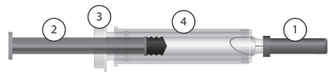
1. Needle shield
2. Plunger
3. Finger-grip
4. Security sleeve

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

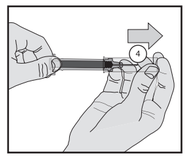


Syringe with a **manual** needle protection system

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**



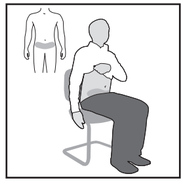
Instructions for use

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 to slightly yellow and doesn't contain particles
   - the syringe has not been opened or damaged

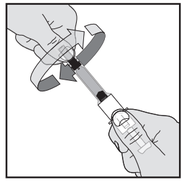
3. **Sit or lie down in a comfortable position.**
   Choose a place in the lower abdominal (tummy) area, at least 5 cm below your belly button (picture **A**).
   Alternate the left and right side of the lower abdominal area at each injection. This will help to reduce the discomfort at the injection 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.

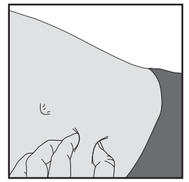


Picture B1

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.

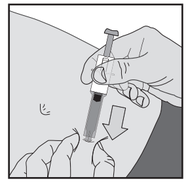
Picture B2

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**).



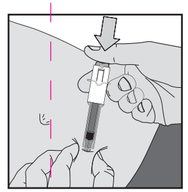
Picture C

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**).



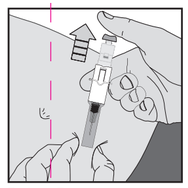
Picture E

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**).

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



Picture F

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

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MA No.	PLGB 46302/0232, PLGB 46302/0233, PLGB 46302/0229	Client Market	United Kingdom		
Supplier SAP No.	N.A.	Barcode Info	N.A.		
New Supplier Code	TBC	3D Render ID	N.A.	Main Font: Frutiger Next	Body Text Size: 8 pt
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Sign-offs					
					V3 MAY 2023