ARIXTRA® 2.5 MG/0.5 ML SOLUTION FOR INJECTION

Fondaparinux sodium (2.5 mg/0.5 ml)

What is in this leaflet

What ARIXTRA is used for

Arixtra 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 movement due to illness
- treat some types of heart attack or severe angina (pain caused by narrowing of the arteries in the heart)

How ARIXTRA works

Arixtra is a medicine that helps to prevent blood clots from forming in the blood vessels (*thromboses*), or treats blood clots if they have already formed (*an antithrombotic agent*). It does this by stopping a clotting factor called Xa ("ten-A") from working in the blood.

Before you use ARIXTRA

- *When you must not use it*

Do not use Arixtra:

- if you are allergic (*hypersensitive*) to fondaparinux sodium or to any of the other ingredients of Arixtra
- if you are bleeding excessively
- if you have a bacterial heart infection
- if you have severe kidney impairment

Check with your doctor if you think any of these may apply to you.

Arixtra should not be prescribed to pregnant women unless clearly necessary. If you are pregnant, or think you could be, tell your doctor.

Breast-feeding is not recommended during treatment with Arixtra.

- *Before you start to use it*

Before you are given Arixtra your doctor needs to know:

- if you have a risk of uncontrolled bleeding (*haemorrhage*) including:
  - stomach ulcer
  - bleeding disorders
  - recent bleeding in the brain (*intracranial bleeding*)
  - recent surgery on the brain, spine or eye
- if you have had blood clotting problems, or a reduction in the number of cells necessary for clotting after previous treatment with heparin (*Heparin Induced Thrombocytopenia*)
- if you have liver disease
- if you have kidney disease
- if you are 75 years old or older
- if you weigh less than 50 kg.

Check with your doctor if you think any of these may apply to you.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines you bought without a prescription. Some other medicines may change the way that Arixtra works or make it more likely you will have side effects such as bleeding.

How to use ARIXTRA

- *How much to use*

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

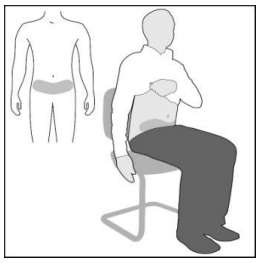
Arixtra is given by injection under the skin (*subcutaneously*) into a skin fold of the lower abdominal area. To treat some types of heart attack, a healthcare professional may give the first dose into a vein (*intravenously*). The syringes are pre-filled with the exact dose you need.

Step-by-step instructions
Parts of the syringes:
①Needle shield
②Plunger
③Finger-grip
④ Security sleeve

Instructions for use

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)



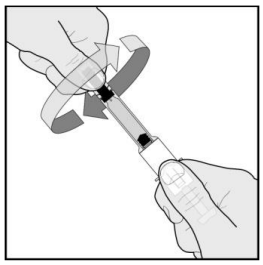
Picture A

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.

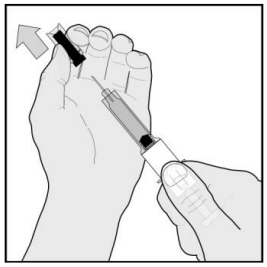
If injecting in the lower abdominal area is not possible, ask your nurse or doctor for advice.

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).



Picture B1

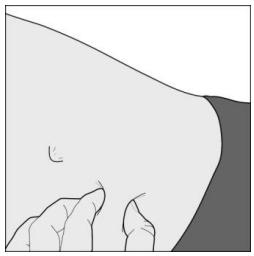


Picture B2

Discard the needle shield.

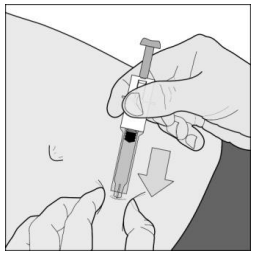
Important note:
Do not touch the needle or allow it to touch any surface before the injection.
It is normal to see a small air bubble in this syringe. Do not try to remove this air bubble before making the injection – you may lose some of the medicine if you do.

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).



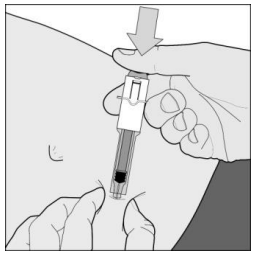
Picture C

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).



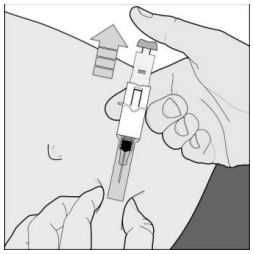
Picture D

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



Picture E

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

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

- *When to use it*

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

- *How long to use it*

The duration of your treatment will depend on your condition. Your doctor will advise you.

Do not stop taking Arixtra without advice. If you stop the treatment before your doctor told you to, you are at higher risk of developing a blood clot in a vein of your leg or lung. Contact your doctor or pharmacist before stopping.

- *If you forget to use it*

If you forget to take a dose, inject it 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.

- *If you use too much (overdose)*

If you accidentally use too much Arixtra, contact your doctor or pharmacist for advice as soon as possible, because you may be at an increased risk of bleeding.

While you are using it
- *Things you must do*

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- *Things you must not do*

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Do not inject Arixtra into muscle.

- *Things to be careful of*

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

The syringe needle shield may contain latex. Tell your doctor if you are allergic to latex.

Side Effects
Like all medicines, Arixtra can cause side effects, although not everybody gets them.

Common side effects
These may affect up to 1 in 10 people:
- bleeding (for example from an operation site, excessive bruising, blood in urine and stool, nosebleed, rarely bleeding can occur in and around the brain or internal organs)
- swelling (*oedema*).

Common side effects that may show up in your blood tests:
- anaemia (a reduction in the number of red blood cells).

Uncommon side effects
These may affect up to 1 in 100 people:
- headache
- feeling sick (*nausea*), vomiting
- rash, itchy skin
- oozing from operation wound site
- fever
- abnormal blood clotting.

Uncommon side effects that may show up in your blood tests:
- 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 1,000 people:
- allergic reaction
- anxiety, confusion
- fainting, dizziness, low blood pressure, spinning sensation (*vertigo)*
- drowsiness, tiredness
- flushing
- coughing, breathlessness
- chest pain, leg pain
- diarrhoea, constipation
- stomach pain, indigestion
- wound infection
- irritation at injection site.

Rare side effects that may show up in your blood tests:
- increase in bilirubin (a substance produced by the liver)
- low potassium.

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of ARIXTRA
- *Storage*

Keep out of the reach and sight of children.
Do not freeze.
Do not use Arixtra:
- after the expiry date stated 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*

If you have any unwanted syringes, do not put them into the household rubbish. Ask your doctor or pharmacist for advice on how to dispose of any syringes you do not need. This will help protect the environment.

Product Description
- *What it looks like*

The solution is a clear and colourless liquid.
It is supplied in a pre-filled, single-use syringe fitted with an automatic safety system to help prevent needle stick injuries after use.

- *Ingredients*
    - Active ingredient

Each syringe contains 2.5 mg of fondaparinux sodium in 0.5 ml solution for injection

- Inactive ingredients

Sodium chloride, hydrochloric acid or sodium hydroxide for pH adjustment as necessary, water for injection.

- *MAL number*

MAL20034441A

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