Arixtra®

Solution for Injection
Fondaparinux sodium

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Arixtra.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Arixtra against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully before you start using Arixtra. You may wish to keep it to read again.

What Arixtra is used for

Arixtra is used to prevent blood clots forming in patients who are recovering from orthopaedic or abdominal surgery. Arixtra is also used to treat blood clots once they have formed. Arixtra contains the medication fondaparinux sodium, a synthetic compound which helps prevent blood clots forming in blood vessels. This type of blood clot, also called deep venous thrombosis, or DVT, can occur in patients who are confined to bed after hip or knee surgery. Arixtra is also used to treat some types of heart attacks and severe angina (a pain caused by narrowing of the arteries in the heart).

Your doctor may have prescribed Arixtra for another reason. Ask your doctor if you have any questions about why Arixtra has been prescribed for you.

Arixtra is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Arixtra

When you must not be given it

You should not be given Arixtra if you have any of the following conditions;

- You are bleeding excessively
- You have severe kidney disease
- You have acute bacterial endocarditis (an infection of the heart)

Do not use Arixtra if you have an allergy to:

- any medicine containing fondaparinux sodium
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Arixtra if you are pregnant or intend to become pregnant.
Arixtra is not recommended for use during pregnancy, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not use Arixtra if you are breast-feeding or plan to breast-feed.
It is not known whether Arixtra passes into human breast milk.

Do not use this medicine in children under the age of 17 years.
Safety and effectiveness in children younger than 17 years have not been established.

Do not use Arixtra after the expiry date (EXP) printed on the pack.
If you use this medicine after the expiry date has passed, it may not work as well as it should.

Do not use Arixtra if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Arixtra, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes
- latex

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.
Your doctor or pharmacist will discuss the possible risks and benefits of using Arixtra during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.
Your doctor or pharmacist will discuss the possible risks and benefits of using Arixtra during breast-feeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- a stomach ulcer
- bleeding disorders
- recent bleeding inside the head
- recent surgery on the brain, eye, or spinal column
- moderate or severe kidney disease or severe liver disease
- heparin induced thrombocytopenia (low platelet count).

Tell your doctor or pharmacist if you are elderly or have a low body weight (less than 50 kg) as you may be at increased risk of bleeding if you are given Arixtra.

It is recommended that your doctor monitor's your blood platelets at the beginning and end of your treatment with Arixtra.

Tell your doctor if you are going to have a stent inserted into your heart.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Arixtra.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.
Some medicines and Arixtra may interfere with each other.

Your doctor or pharmacist have more information on medicines to be careful with or to avoid while using Arixtra.

How Arixtra is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much is given

The usual dose of Arixtra is 2.5 mg given once a day, starting after your operation. Arixtra may be given for up to 31 days.

How it is given

Arixtra is given to you as a subcutaneous injection (an injection just under the skin). To treat some types of heart attack, the health professional only may give the first dose intravenously (into a vein).

Arixtra should NOT be given as an intramuscular injection (an injection into the muscle).

The injections can be given by a doctor or nurse, or you may be taught how to give the **subcutaneous** injections to yourself.

Instructions on how to use the Arixtra syringe **subcutaneously** are given at the end of this leaflet.

Overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Arixtra. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Overdose may lead to an increased risk of bleeding.

While you are using Arixtra

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Arixtra.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Arixtra.

Immediately tell your doctor if you develop the following:

- pain or swelling in the legs
- chest pain or difficulty in breathing

These may be signs that a blood clot has formed.

If you have epidural or spinal anaesthesia (a pain killing injection around the spinal cord), tell your doctor or nurse immediately if you have back pain, numbness or weakness in the legs, or problems with bowel or bladder function.

Things you must not do

Do not use Arixtra to treat any other complaints unless your doctor or pharmacist tells you to. Do not give

Arixtra to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Arixtra.
Arixtra helps most people at risk of blood clots following surgery, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using Arixtra without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following:

- bleeding
- oozing of fluid from the wound
- unusual tiredness, weakness or drowsiness
- fever
- nausea or vomiting
- indigestion or gastritis
- low blood pressure
- fainting or vertigo
- dizziness or confusion
- difficulty sleeping
- pain or skin reactions at the injection site
- itching sensation on the skin
- urinary tract infection
- difficulty or pain when passing urine
- diarrhoea or constipation
- headache
- coughing
- swelling (oedema)
- shortness of breath
- flushing of the skin

These side effects of Arixtra are usually mild.

Tell your doctor or pharmacist immediately if you notice any of the following:

- allergic reaction. Symptoms of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing,
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
- significant bleeding

These may be signs of serious side effects. You may need urgent medical attention. Serious side effects are rare.

The following side effects may be identified by tests performed by your doctor:

- blood disorders such as decreased or abnormal blood platelets, clotting disorders or excess bilirubin
- changes in liver function or liver enzymes

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After using Arixtra

Storage

Arixtra will normally be stored in the pharmacy or on the hospital ward. The injection should be kept at room temperature (less than 25°C).

Disposal

If your doctor or pharmacist tells you to stop using Arixtra or the injections have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Arixtra comes as a pre-filled safety syringe, in pack sizes of 2 pre-filled syringes.

Ingredients

Active ingredients:

- fondaparinux sodium

Other ingredients

- sodium chloride
- water for injections

Distributor

Arixtra is supplied in Australia by;

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Arixtra has the following registration No:
2.5 mg - AUST R 80279

This leaflet was updated in September 2018

Method of administration

Arixtra is administered by **subcutaneous injection (an injection just under the skin).** Arixtra is for single use in one patient only. Discard any residue.

The solution should be inspected visually for particles and discoloration prior to administration. If present, do not proceed with the injection.

Subcutaneous administration

The sites of subcutaneous injection should be on the fatty tissues on the abdominal area. It is important to alternate between the left and the right sides. To avoid the loss of medicinal product when using the pre-filled syringe do not expel the air bubble from the syringe before injection. The whole length of the needle should be inserted between the thumb and forefinger (see figures 2 and 3). The skin fold should be held throughout the injection.

Arixtra is intended for use under a physician's guidance. Patient's may self-inject only if their physician determines that it is appropriate, and with medical follow-up as necessary. Proper training in **subcutaneous injection** technique should be provided. Instructions for self-administration **subcutaneously** are included below.

The parts of the syringe with an automatic needle protection system are:

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

To use the Arixtra syringe, remove the needle shield, by first twisting it and then pulling it straight off (figure 1).

Discard the needle shield.

Figure 1

For ***subcutaneous*** administration:

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 (figure 2).

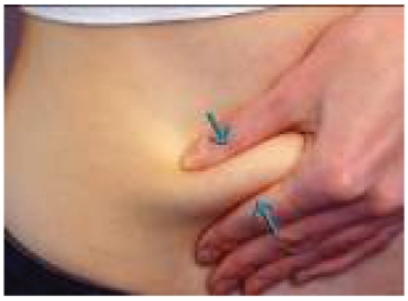

Figure 2

Insert the full length of the needle perpendicularly (at an angle of 90°) into the skin fold (figure 3).

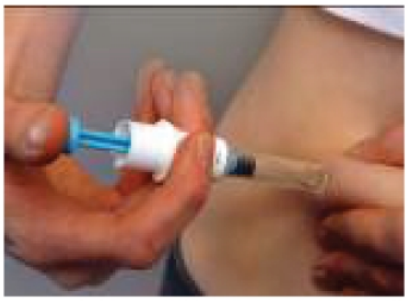

Figure 3

Inject ALL of the content of the syringe by pressing down on the plunger as far as it goes (figure 4), and then release it: the needle will withdraw automatically from the skin into a security sleeve and then will be locked permanently (figure 5).

Figure 4

Figure 5

Discard the used syringe in a safe manner by using a sharps disposal container. This is usually available at the local community pharmacy.