1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

ARIXTRA 2,5 mg/0,5 ml solution for injection - Pre-filled syringes

Fondaparinux sodium

Sugar free

Read all of this leaflet carefully before you start using ARIXTRA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ARIXTRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ARIXTRA is and what it is used for

ARIXTRA is a type of medicine called an antithrombotic.

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.
- reduce the risk of the formation of blood clots in the blood vessels of the legs or lungs during and shortly after a period of restricted mobility due to acute illness such as heart failure, lung diseases and/or infectious or inflammatory disease.
- treat some types of heart attack and severe angina (pain caused by narrowing of the arteries in the heart).

2. What you need to know before you use ARIXTRA

Do not use ARIXTRA:

- if you are hypersensitive (allergic) to fondaparinux sodium or any of the other ingredients of ARIXTRA (listed in section 6).
- if you suffer from bacterial infection of the heart (bacterial endocarditis).
- if you have any bleeding.
- if you suffer from severe kidney disease.
- if you have had recent brain, spinal column, eye or ear injuries.
- if you weigh less than 50 kg.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with ARIXTRA:

- if you have a risk of uncontrolled bleeding (haemorrhage) including stomach ulcers and bleeding disorders.

- if you have had blood clotting problems, or a reduction in the number of cells necessary for clotting after previous treatment with heparin.
- if you have liver disease.
- if you have kidney disease.
- if you are elderly (65 years old or older).
- if you have had an operation, the first dose of ARIXTRA should be administered about 6 hours after surgery and only once any bleeding has stopped from the wound site. As this medicine prevents blood clotting, giving ARIXTRA before this time may make the bleeding worse.

If you are having an epidural anaesthetic, a spinal anaesthetic or if a sample of fluid is being taken from the space around the spine (lumbar puncture), while you are using ARIXTRA, there is a risk of bleeding into the spine at the site of the injection, which can be serious. If you have any concerns you should discuss these with your doctor.

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

Children and adolescents

ARIXTRA should not be given to children and adolescents under the age of 18.

Other medicines and ARIXTRA

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Other medicines that can affect blood clotting should not be taken with ARIXTRA unless specifically prescribed by your doctor.

Pregnancy, breastfeeding and fertility

You should not use ARIXTRA if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ARIXTRA.

Driving and using machines

It is not always possible to predict to what extent ARIXTRA may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment until you are aware of the measure to which ARIXTRA affects you (see section 4).

3. How to use ARIXTRA

Do not share medicines prescribed for you with any other person.
Always use ARIXTRA exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are unsure.

Dosage:

ARIXTRA is given by injection under the skin (subcutaneous injection).
To treat some types of heart attack, the first dose may be given intravenously (into the vein).
The usual dose of ARIXTRA for preventing blood clots forming is 2,5 mg once a day. If you have reduced kidney function, your doctor may decide that this dose be given every other day. The usual duration of treatment

following surgery is 7±2 days and for as long as the risk of VTE is still current.

The usual duration of treatment for a heart attack or severe angina, is up to 8 days or until discharge from hospital.

The usual duration of treatment for use after restricted mobility is 6 to 14 days.

Your doctor will tell you how long your treatment with ARIXTRA will last. Do not stop treatment early. If you have the impression that the effect of ARIXTRA is too strong or too weak, tell your doctor or pharmacist.

Administration

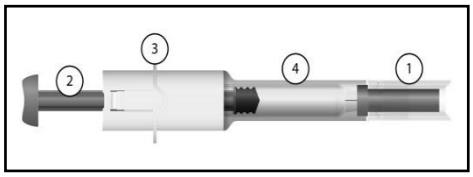
ARIXTRA is injected into a skin fold of the lower abdominal area. It must not be injected into muscle. While usually a healthcare provider will administer this injection, in some cases you may be taught how to do this yourself. You should follow carefully the step-by-step instructions, as included in this leaflet, on how to self-administer ARIXTRA.

Always use ARIXTRA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. **Do not stop** ARIXTRA treatment before your doctor tells you to.

Instructions for self-administration

The different parts of ARIXTRA safety syringe are:

1. Rigid needle sheath
2. Plunger
3. Finger-grip
4. Security sleeve



1. Wash your hands thoroughly with soap and water. Towel dry.
2. Remove the syringe from the carton and check that the expiry date has not passed and that the syringe has not been opened or damaged.
3. Sit or lie down in a comfortable position.

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

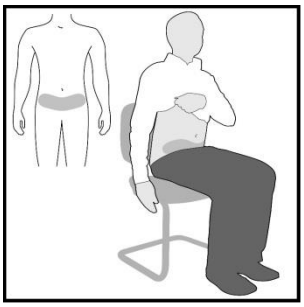


Figure A

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

   Discard the needle guard.

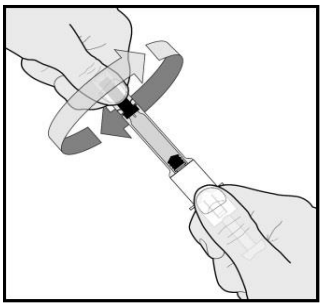


Figure B1

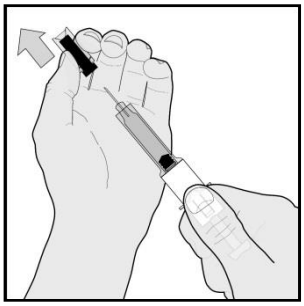


Figure B2

Important note:

- Do not touch the needle or allow it to come in contact with any surface before the injection
- The presence of a small air bubble in the syringe is normal. 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 (figure C).

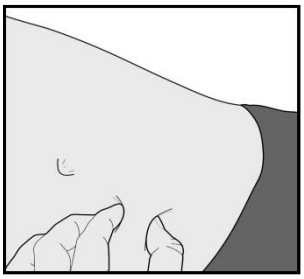


Figure C

7. Hold the syringe firmly by the finger grip. Insert the full length of the needle at right angles into the skin fold (figure D).

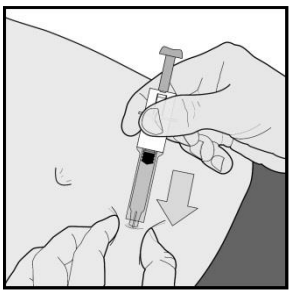


Figure D

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

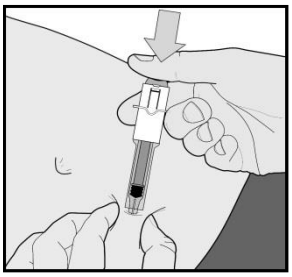


Figure E

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 (figure F).

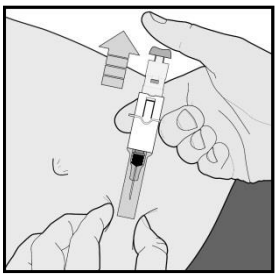


Figure F

10. Do not dispose of the used syringe in the household waste.

Dispose of it as your nurse or doctor has instructed.

If you use more ARIXTRA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital, or poison control centre.

Overdosage increases your risk of bleeding problems.

If you forget to use ARIXTRA

Do not inject a double dose to make up for forgotten individual doses.

4. Possible side effects

ARIXTRA can have side effects.

Not all side effects reported for ARIXTRA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using ARIXTRA, please consult your healthcare provider for advice.

If any of the following happens, stop using ARIXTRA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ARIXTRA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bleeding, which can be serious (e.g. from an operation, excessive bruising, blood in urine and stool, in and around the brain or internal organs),
- breathing difficulties,
- chest pain,
- increase in bilirubin (substance produced by the liver) causing yellowing of skin and eyes (known as jaundice).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects :

- Nosebleed,

- anaemia (a reduction in the number of red blood cells, making you feel very tired),
- having trouble sleeping (insomnia),
- pain on urination and feeling the need to urinate frequently even when the bladder is empty (urinary tract infection),
- bruising or swelling (oedema) and swelling of the lower legs or hands (peripheral oedema).

Less frequent side effects:

- nausea (feeling sick), vomiting (being sick),
- headache,
- oozing from operation wound site,
- fever,
- abnormal blood clotting,
- reduction or increase in the number of platelets (blood cells necessary for blood clotting), as seen in your blood tests,
- changes in liver blood tests,
- difficulty urinating (urinary retention),
- infection of wound at site of surgery,
- irritation at injection site,
- anxiety, confusion,
- dizziness, low blood pressure, spinning sensation (vertigo),

- drowsiness, tiredness,
- flushing,
- coughing,
- leg pain,
- stomach pain, diarrhoea, constipation, indigestion,
- low potassium levels in your blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ARIXTRA.

5. How to store ARIXTRA

Store all medicines out of reach of children.

Do not freeze.

Store at or below 25 ºC.

Do not store in a bathroom.

Do not use ARIXTRA:

- after the expiry date stated on the label and carton;
- if you notice any particles in the solution;
- if the solution is discoloured. The 2,5 mg solution should be colourless;
- if you notice that the syringe is damaged;
- if you have opened a syringe and you do not intend to use it straightaway.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ARIXTRA contains

The active substance in each pre-filled syringe of ARIXTRA 2,5 mg/0,5 ml is 2,5 mg of fondaparinux sodium in 0,5 ml of an isotonic solution.
The other ingredients are hydrochloric acid (for pH adjustment), sodium chloride, sodium hydroxide (for pH adjustment), water for injection.
Sugar free.

What ARIXTRA looks like and contents of the pack

ARIXTRA 2,5 mg/0,5 ml is in a pre-filled glass syringe containing a clear to practically clear and colourless solution, free from visible particles.

Pre-filled, single use, clear and colourless glass syringe with a blue plunger affixed with a 27 gauge (0,4 mm) x 12,7 mm needle and an automatic safety system. 2, 7, 10 and 20 syringes are packed in an outer cardboard carton.

Not all pack sizes are necessarily marketed.
The needle protection system of the ARIXTRA 2,5 mg/0,5 ml pre-filled syringe has been designed to protect healthcare providers from needle stick injuries following injection.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 118 088

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient

Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088