PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a physician's prescription only

Arixtra 7.5 mg/0.6 ml

Solution for injection

The active ingredient and its concentration:

12.5 mg Fondaparinux sodium in 1 ml solution for injection

Inactive ingredients and allergens in the medicine – see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information" in this leaflet.

Read the leaflet carefully in its entirety before using the medicine, as it contains important information for you. This leaflet contains concise information about the medicine. Keep the leaflet; you may need to read it again. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

If side effects occur, including side effects not mentioned in section 4 of this leaflet, inform the physician or pharmacist.

1. WHAT IS THE MEDICINE INTENDED 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 that 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).

Therapeutic group:

Anticoagulant.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **you are sensitive (allergic)** to the active ingredient fondaparinux sodium or to any of the other ingredients contained in the medicine as listed in section 6
- **you are bleeding excessively**
- **you have a bacterial heart infection**
- **you have severe kidney disease**

Tell your physician if you think any of these apply to you. If they do, you must **not** use Arixtra.

Special warnings regarding use of the medicine

Before treatment with Arixtra, tell the physician if:

- **you have had previous complications during treatment with heparin or heparin-like medicines that caused a reduction in the number of blood platelets (heparin-induced thrombocytopenia).**
- **you have a risk of uncontrolled bleeding** (haemorrhage) including:
  - **stomach ulcer**
  - **bleeding-related disorders**
  - recent **bleeding into the brain** (intracranial bleeding)
  - **recent surgery** on the brain, spine or eye
- **you have severe liver disease**
- **you have kidney disease**
- **you are 75 years old or older**

Tell your physician if any of these apply to you.

Children and adolescents

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

Drug interactions

If you are taking, have recently taken, or might take any other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. 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 become pregnant, consult the physician or the pharmacist before using the medicine.

Important information about some of the ingredients of the medicine

Arixtra contains sodium

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

Arixtra syringe contain latex

The syringe needle shield contains latex, which may cause allergic reactions among people sensitive to latex.

Tell your physician if you are allergic to latex before starting treatment with Arixtra.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the physician only. **The usual dosage is generally:**

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.

Do not exceed the recommended dose.

Treatment duration

You should continue Arixtra treatment for as long as your physician has told you, since Arixtra prevents development of a serious medical condition.

Method of administration:

- 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. **For step-by-step instructions please see over the page.**
- Do **not** inject Arixtra into muscle.

If you accidently have taken a higher dosage you should contact your physician or pharmacist for advice as soon as possible, because of the increased risk of bleeding.

If you took an overdose or if a child or someone else has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

- **Take the medicine 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 physician or pharmacist.

Adhere to the treatment regimen as recommended by the physician.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician or the pharmacist.

If you stop taking the medicine –

Do not stop using this medicine without consultation

If you stop the treatment before your physician 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 physician or pharmacist before stopping the treatment.**

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Arixtra may cause side effects in some of the users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Conditions you need to look out for

Severe allergic reactions (anaphylaxis): These reactions are very rare in people taking Arixtra (occur in less than 1 user in 10,000). Signs include:

- swelling, sometimes of the face or mouth (angioedema), causing difficulty in swallowing or breathing
- collapse

Contact a physician immediately if you get these symptoms. **Stop taking Arixtra.**

Additional side effects

Common side effects (occur in 1-10 in 100 users)

- **bleeding** (for example, from an operation site, an existing stomach ulcer, nose, bruising)

Uncommon side effects (occur in 1-10 in 1,000 users)

swelling (oedema); headache; pain; feeling sick or being sick (nausea or vomiting); low number of red blood cells (anaemia); low number of platelets (blood cells necessary for blood clotting); increase in chemicals (*enzymes*) produced by the liver

Rare side effects (occur in 1-10 in 10,000 users)

allergic reaction (including itching, swelling, rash); internal bleeding in the brain, liver or abdomen; rash; dizziness; pain and swelling at injection site; high number of platelets (blood cells necessary for blood clotting); increase in the amount of non-protein nitrogen in the blood; stomach pain; itching; indigestion; diarrhoea or constipation; increase in bilirubin (a substance produced by the liver) in the blood

If a side effect occurs, if one of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form of reporting side effects, or by entering the link: https://sideeffects.health.gov.il

Additionally, side effects can be reported to the company via the following address:

Padagis.co.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
  Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton. The expiry date refers to the last day of that month.
- Store below 25°C. Do not freeze.

Do not use this medicine if:

- you notice any particles in the solution, or if the solution is discoloured.
- you notice that the syringe is damaged.
- you have opened a syringe and you do not use it straightaway.

Syringe disposal:

Do not throw medicines or syringes in the wastewater or household waste. Ask the pharmacist how to dispose of medicines that you no longer use. This will help preserve the environment.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredient the medicine also contains:**
  Sodium chloride, water for injections, hydrochloric acid and/or sodium hydroxide to adjust the pH.
  Arixtra does not contain any animal products.
- **What does the medicine look like and what is the content of the package:**
  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.
- The medicine is available in packs of 2, 7, 10 and 20 pre-filled syringes.
- Not all pack sizes may be marketed.
- **Registration holder:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- **Manufacturer:** Aspen Notre Dame de Bondeville, Notre Dame de Bondeville, France.
- Revised in March 2022 according to MOH guidelines.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 13952.31589

STEP-BY-STEP GUIDE TO USING ARIXTRA

Instructions for use

Parts of the syringe:

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

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

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

Picture A

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 physician for advice.

Picture B1

4. **Clean the injection area with an alcohol wipe.**

Picture B2

5. **Remove the needle shield.** First twist it (picture **B1**), and then pull 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 C

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 D

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**).
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**).

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

Picture F