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: 7.5 mg Fondaparinux sodium in 0.6 ml solution for injection

List of the other ingredients are listed in section 6.

Read the entire leaflet carefully 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.

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 doctor 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

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 resolution.

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 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 applies
 to you. If they do, you must not use Arixtra.

- Special warnings regarding the use of the medicine
 Before the treatment with Arixtra, tell the physician

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 (haemorrhage) including: uncontrolled bleeding
- stomach ulcer bleeding-related disorders
- recent b bleeding into the brain (intracranial
- 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 applies 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 food 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 ingredients of

the 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, 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. with the physician or pharmacist if you are about the dosage and treatment regimen of

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

Your weight Usual dose

Below 50 kg 5 mg once a day Between 50 kg and 100 7.5 mg once a day

kg

-	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

the page

Do not inject Arixtra into muscle. If you accidently have taken a higher dosage yo should contact your physician or pharmacist for advias soon as possible, because of the increased risk bleeding.

bleeding. If you took an overdose or if someone 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 dose as soon inject a double dose to n as you remember. Do not to make up for a forgotten

dose. If you are not sure what to do, ask your physician or

- pharmacist. Persist with the treatment 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 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.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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 with

any medicine, use of Arixtra may cause side in some of the users. Do not be alarmed by the list of side effects. You may not experience reading the i Conditions you need to look out for

Severe allergic reactions (anaphylaxis): These are very rare in people taking Arixtra (occur in up to 1 in 10,000 rare in people taking Ari patients). Signs include:

outh (angioedema),

swelling, sometimes of the face or mouth (angi-causing difficulty in swallowing or breathing

patients)

collapse Contact a physician immediately if you get these symptoms. Stop taking Arixtra. Additional side effects

Common side effects (occur in more than 1 in 100

bleeding (for example from an operation site, an existing stomach ulcer, nose, bruising) Uncommon side effects (occur in up to 1 in patients)

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 (narawase) produced by the liver. necessary for blood clotting); (enzymes) produced by the liver

Rare side effects (occur in up to 1 in 1,000 patients) 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 rash): clotting); 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 any of the side effects get worse, or when you suffer from side effect not mentioned in the leaflet, you should consult the physician.

Reporting side effects:

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

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il
In addition, you can report to Perrigo via the following address: www.perrigo-pharma.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 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 waste water 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 colorless 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: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer: Aspen Notre Dame de Bondeville, Notre Dame de Bondeville, France.
- The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in August 2013 and was updated in accordance with the Ministry of Health guidelines in October 2018.
- 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
- Security sleeve
- 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

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.

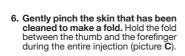
4. Clean the injection area with an alcohol wipe.



Discard the needle shield.

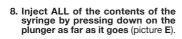
Important note

- 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 the syringe. Do not try to remove this air bubble before making the injection you may lose some of the medicine if you do.



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).



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.

איור 1. מזרק עם מערכת אוטומטית להגנת מחט

الصورة ١. محقنة مع منظومة آلية لحماية الإبرة



Picture 1. Syringe with an automatic needle protection system



Picture A איור א سورةأ



Picture B1 איור ב1 الصورة ب١



22 איור Picture B2 سورة ب٢



Picture C الصورة ج



איור ד Picture D ىورة د



Picture E איור ה



איור ו