

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
- ④ Security sleeve

איור 1. מערכת אוטומטית להגנת מחט

الصورة ١. محقنة مع منظومة آلية لحماية الإبرة



Picture 1. Syringe with an automatic needle protection system

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 to slightly yellow and doesn't contain particles
- the syringe has not been opened or damaged



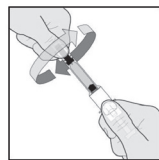
Picture A איור א
الصورة أ

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.

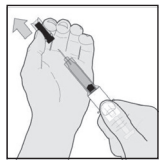


Picture B1 איור ב1
الصورة ب١

4. Clean the injection area with an alcohol wipe.

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).

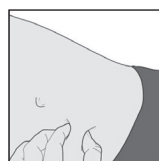
Discard the needle shield.



Picture B2 איור ב2
الصورة ب٢

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.

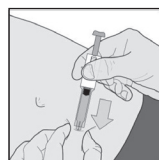


Picture C איור ג
الصورة ج

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).

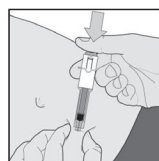
7. Hold the syringe firmly by the finger grip.

Insert the full length of the needle at right angles into the skin fold (picture D).



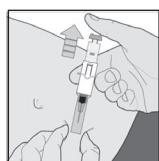
Picture D איור ד
الصورة د

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



Picture E איור ה
الصورة هـ

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 איור ו
الصورة و

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