

The following information is intended for healthcare professionals only:

Fulvestrant Teva 500 mg (2 x 250 mg/5 ml solution for injection) should be administered using two pre-filled syringes.

Instructions for administration

Administer the injection according to the local guidelines for performing large volume intramuscular injections.

NOTE: Due to the proximity of the underlying sciatic nerve, caution should be taken if administering Fulvestrant Teva at the dorsogluteal injections site.

Warning - **Do not** autoclave safety needle before use. Hands **must** remain behind the needle at all times during use and disposal.

For each of the two syringes:

- Remove glass syringe barrel from tray and check that it is not damaged.
- Peel open the safety needle outer packaging.
- Parental solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully twist the cap counter-clockwise until the cap disconnects for removal (see Figure 1).

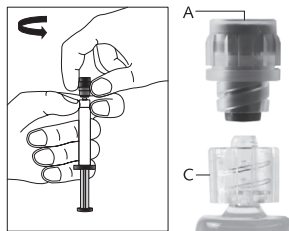


Figure 1

- Remove the cap (A) off in a straight upward direction. To maintain sterility **DO NOT TOUCH THE STERILE SYRINGE TIP (Luer-Lock) (B)** (see Figure 2).

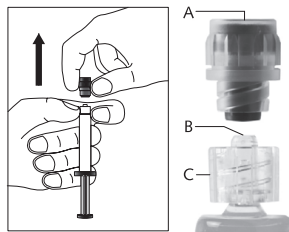


Figure 2

- Attach the safety needle to the Luer-Lock and twist until firmly seated (see Figure 3).
- Check that the needle is locked to the Luer connector

before moving out of the vertical plane.

- Transport filled syringe to point of administration.
- Pull shield straight off needle to avoid damaging needle point.

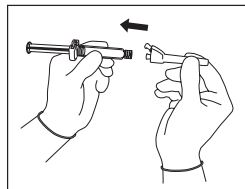


Figure 3

- Expel excess gas from the syringe.
- Administer intramuscularly slowly (1-2 minutes/injection) into the buttock (gluteal area). For user convenience, the needle bevel-up position is oriented to the lever arm (see Figure 4).

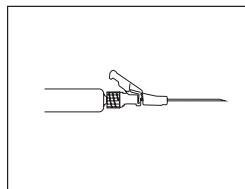


Figure 4

- After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the needle shielding mechanism (see Figure 5). NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

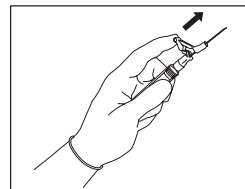


Figure 5

Disposal

Pre-filled syringes are for single use **only**.

This medicine may pose a risk to the aquatic environment. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.