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Both syringes must be administered to receive the 500 mg dose.

USUAL DOSAGE: See Prescribing Information for details of administration. See below for assembly instructions.

STORAGE: REFRIGERATE, 2–8°C (36–46°F). TO PROTECT FROM LIGHT, STORE IN THE ORIGINAL CARTON UNTIL TIME OF USE.

WARNING: As with all medications, keep out of the reach of children.

Carton contains: A total of 500 mg fulvestrant in TWO pre-filled syringes each containing 250 mg/5 mL, and two SafetyGlide™ shielding intramuscular injection needles.

FASLODEX® also contains as inactive ingredients: Alcohol, USP; Benzyl Alcohol, NF; and Benzyl Benzoate, USP, as co-solvents; and Castor Oil, USP as a co-solvent and release rate modifier.

INSTRUCTIONS FOR INTRAMUSCULAR USE:

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 FASLODEX at the dorsogluteal injection site.

1. Remove glass syringe barrel from tray and check that it is not damaged.
2. Remove perforated patient record label from syringe.
3. Inspect drug product in glass syringe for any visible particulate matter or discoloration prior to use. Discard if particulate matter or discoloration is present.
4. Peel open the safety needle (SafetyGlide™) outer packaging.
5. Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully tilt cap back and forth (DO NOT TWIST CAP) until the cap disconnects for removal (see Figure 1).
6. Pull the cap (A) off in a straight upward direction. DO NOT TOUCH THE STERILE SYRINGE TIP (Luer-Lok) (B) (see Figure 2).

Figure 1

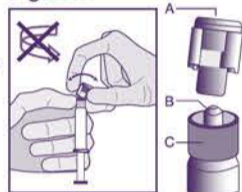
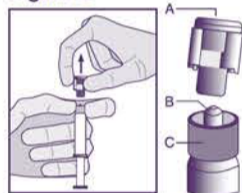
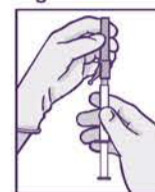


Figure 2



7. Attach the safety needle to the syringe tip (Luer-Lok). Twist needle until firmly seated (see Figure 3). Confirm that the needle is locked to the Luer connector before moving or tilting the syringe out of the vertical plane to avoid spillage of syringe contents.

Figure 3



For Administration:

8. Pull shield straight off needle to avoid damaging needle point.
9. Remove needle sheath.
10. Expel excess gas from the syringe (a small gas bubble may remain).
11. Administer intramuscularly slowly (1-2 minutes/injection) into the buttock (gluteal area). For user convenience, the needle 'bevel up' position is orientated to the lever arm, as shown in Figure 4.
12. After injection, immediately activate the lever arm to deploy the needle shielding by applying a single-finger stroke to the activation assisted lever arm to push the lever arm completely forward. Listen for a click. Confirm that the needle shielding has completely covered the needle (see Figure 5). NOTE: Activate away from self and others.
13. Discard the empty single use syringe into an approved sharps collector in accordance with applicable regulations and institutional policy.
14. Repeat steps 1 through 13 for second syringe.

Figure 4

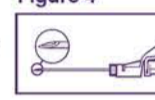
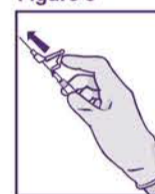


Figure 5



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Product of Germany

FASLODEX®
fulvestrant injection
250 mg / 5 mL
Both syringes must be administered to receive the 500 mg dose

OPEN HERE

FASLODEX®
fulvestrant injection

250 mg / 5 mL

Both syringes must be administered to receive the 500 mg dose

For Single-Patient Use Only

FASLODEX®
fulvestrant injection

250 mg / 5 mL

For Intramuscular Use Only

NDC 0310-0720-10

This carton contains a total of 500 mg fulvestrant in TWO pre-filled syringes each containing 250 mg/5 mL, and two SafetyGlide™ shielding intramuscular injection needles.

Both syringes must be administered to receive the 500 mg dose.

REFRIGERATE, 2–8°C (36–46°F). TO PROTECT FROM LIGHT, STORE IN THE ORIGINAL CARTON UNTIL TIME OF USE.

Rx only

Contains **2**
pre-filled
syringes

AstraZeneca

FASLODEX®
fulvestrant injection

250 mg / 5 mL

Both syringes must be administered to receive the 500 mg dose



3 0310-0720-10 7

PERFORATED AREA

TAMPER EVIDENT SECURITY LABEL MAY NOT BE APPLIED TO ALL PACKS

TAMPER EVIDENT SECURITY LABEL POSITION

VARNISH-FREE

RESERVED AREA

AstraZeneca

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AMNA IBRAHIM

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