

US
N028215/02

Fulvestrant Injection

250 mg per 5 mL (50 mg per mL)

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

For Single-Dose Only

NDC 63323-715-05

Fulvestrant Injection

250 mg per 5 mL (50 mg per mL)

For intramuscular use only.

This carton contains a total of 500 mg fulvestrant in TWO pre-filled syringes each containing 250 mg per 5 mL (50 mg per mL), and two SafetyGlide™ shielding intramuscular injection needles.

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

STORE AT: 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature]

Do not freeze.
To protect from light, store in the original carton until time of use.

Contains 2 pre-filled syringes
Rx only



Open here

Fulvestrant Injection

250 mg per 5 mL (50 mg per mL)

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

621576B

Lot:
Exp:
SN:

Fulvestrant Injection

250 mg per 5 mL (50 mg per mL)

Fulvestrant Injection

250 mg per 5 mL (50 mg per mL)

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

Sample label. Please see package insert for complete prescribing information.



(01)20363323715056

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.

STORE AT: 20°C to 25°C (68°F to 77°F) [USP Controlled Room Temperature].

Do not freeze.

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 per 5 mL (50 mg per mL), and two SafetyGlide™ shielding intramuscular injection needles.

Fulvestrant Injection also contains as inactive ingredients: Dehydrated Alcohol, USP and Benzyl Alcohol, NF as co-solvents; Polysorbate 80, NF as a solubilizing agent; Alpha-Tocopherol, USP as a stabilizing agent; 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 Fulvestrant Injection at the dorsogluteal injection site.

1. Remove glass syringe barrel from tray and check that it is not damaged.
2. Inspect drug product in glass syringe for any visible particulate matter or discoloration prior to use. Discard if particulate matter or discoloration is present.
3. Peel open the safety needle (SafetyGlide™) outer packaging.
4. Hold the syringe upright. Twist and remove the Luer tip cap (see Figure 1).
5. Do not touch the Sterile Syringe Tip (Luer-Lok).

Figure 1

5. Attach the safety needle to the syringe tip (Luer-Lok). Twist needle until firmly seated (see Figure 2). 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.

For Administration:

Figure 2

7. Pull needle cap straight off needle to avoid damaging needle point.

8. Expel excess gas from the syringe (a small gas bubble may remain).

9. 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 3.

10. After injection, immediately activate the lever arm to deploy the safety shield 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 safety shield has completely covered the needle (see Figure 4).

NOTE: Activate away from self and others.

11. Discard the empty syringe into an approved sharps collector in accordance with applicable regulations and institutional policy.

12. Repeat steps 1 through 11 for second syringe.

SafetyGlide™ is a trademark of Becton Dickinson and Company.

Mfd. for:
FRESENIUS KABI
Lake Zurich, IL 60047
Made in Austria

Figure 3

Figure 4

