

FULVESTRANT - fulvestrant injection, solution
Zydus Lifesciences Limited

Fulvestrant Injection

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1626-2

Fulvestrant Injection

250 mg/5 mL (50 mg/mL)

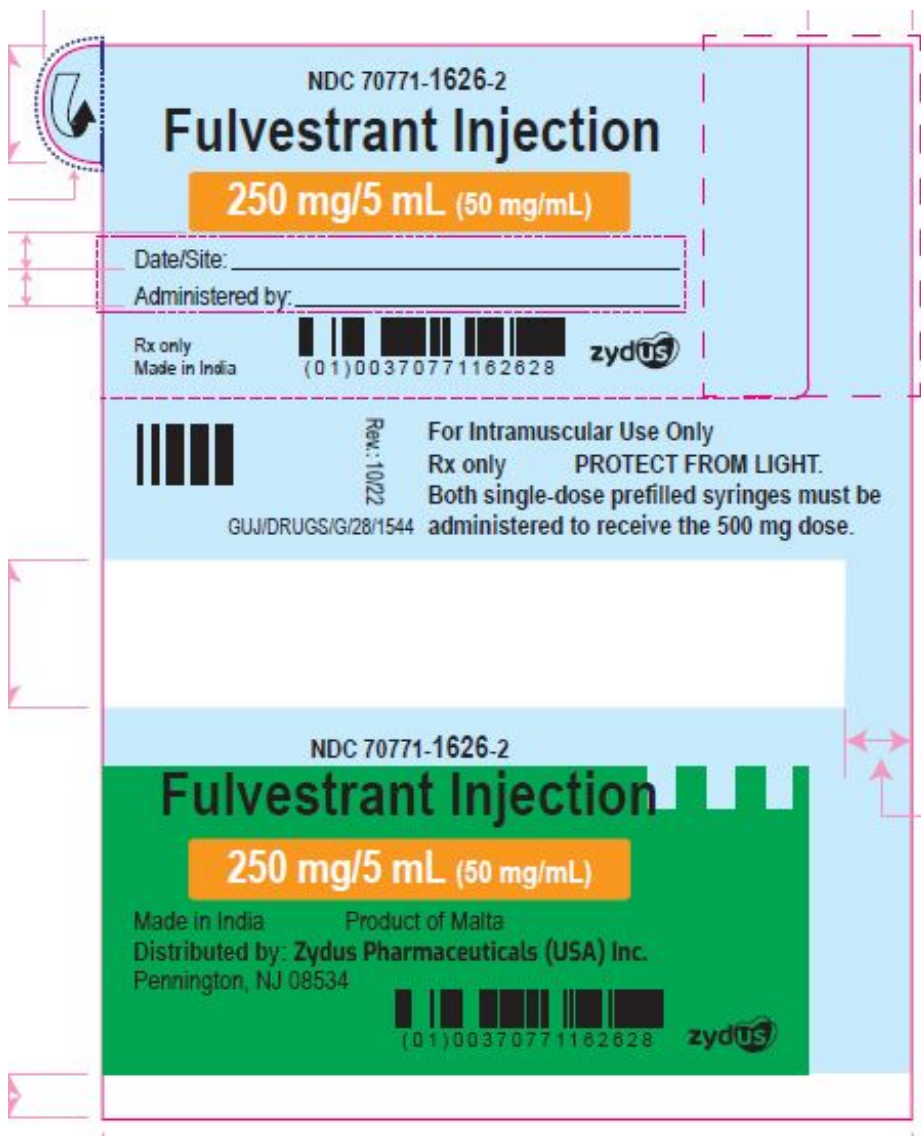
For Intramuscular Use Only

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

PROTECT FROM LIGHT

Rx only

Made in India



NDC 70771-1626-8

Fulvestrant Injection

250 mg/5 mL (50 mg/mL)

For Intramuscular Use Only

This carton contains a total of 500 mg fulvestrant in TWO single-dose prefilled syringes each containing 250 mg/5 mL, and two Safety Glide™ shielding intramuscular injection needles.

Discard each syringe after use.

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

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

Contains 2 Single-Dose Prefilled Syringes

Rx only

Over Coding Template
Size : 37 x 143 mm

Both single-dose prefilled 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° to 8°C (36° to 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 single-dose prefilled syringes each containing 250 mg/5 mL (50 mg/mL), and two SafetyGlide™ shielding intramuscular injection needles. Fulvestrant Injection also contains as inactive ingredients: 10% w/v Alcohol, USP, 10% w/v Benzyl Alcohol, NF, and 15% w/v Benzyl Benzoate, USP, as co-solvents, and made up to 100% w/v with 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. 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

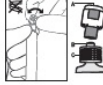
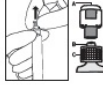


Figure 2



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 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



SafetyGlide™ is a trademark of Becton Dickinson and Company.

GUIDRUGS/G28/1544

Product of Mata

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India



143 mm

38 mm

Rev: 10/22

Fulvestrant Injection

250 mg/5 mL (50 mg/mL)

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NDC 70771-1626-8

XXXXXXXX

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FULVESTRANT

fulvestrant injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1626
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
FULVESTRANT (UNII: 22X328QOC4) (FULVESTRANT - UNII:22X328QOC4)		FULVESTRANT	50 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
ALCOHOL (UNII: 3K9958V90M)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
BENZYL BENZOATE (UNII: N863NB338G)				
CASTOR OIL (UNII: D5340Y2I9G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1626-8	2 in 1 CARTON	12/14/2021	
1	NDC:70771-1626-2	5 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA215234	12/14/2021		

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677604722	ANALYSIS(70771-1626) , MANUFACTURE(70771-1626)

Revised: 8/2022

Zydus Lifesciences Limited