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™ protecting intramuscular injection needles. FASLODEX® also contains as inactive ingredients: Alcohol, USP; Benzyl Alcohol, NF; and Benzel Benzoate, USP; as co-solvents; and Cetyl Alcohol, USP as a co-solvent and release retarder.

INSTRUCTIONS FOR INTRAMUSCULAR USE:

1. Remove or discard patient record label from syringe.
2. Invert and gently shake to mix the contents of the syringe.
3. Use only the needle shielded intramuscular injection needle (see Figure 2). Do not use needles that are not shielded.
4. Remove the needle shield and discard it in the appropriate sharps container (see Figure 4).
5. Hold the syringe perpendicular to the skin and press the plunger to expel all air and grasp the outer barrel with the dominant hand and the plunger grip with the non-dominant hand. Apply steady, moderate pressure to the plunger. Release the plunger and expel any air that remains in the syringe. Do not recap the needle.
6. Inject the solution into the muscle mass (see Figure 5).
7. Remove the needle and discard it in the appropriate sharps container (see Figure 4).

For Intramuscular Use Only

FASLODEX® fulvestrant injection

250 mg / 5 mL

Rx only

Contains 2 pre-filled syringes

NDC 0310-0720-10

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

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/s/

AMNA IBRAHIM
01/24/2017