4 CONTRAINDICATIONS

Abblock® (fulvestrant) injection, for intramuscular use in syringes containing 250 mg/5 mL fulvestrant.

Becton Dickinson guarantees the contents of their unopened or undamaged packages to be sterile, and that they do not impart any of their chemical properties to the product contained in them.

To help avoid HIV (AIDS), HBV (Hepatitis), and other infectious diseases due to accidental needle-stick or needle-prick injuries, it is recommended that each SafetyGlide® Needle be used only once. Do not autoclave SafetyGlide® Needle before use.

• Injection Site Reaction [see Warnings and Precautions (5.3)]

When Fulvestrant Injection is used in combination with palbociclib, abemaciclib, or ribociclib, refer to abemaciclib, or ribociclib, should be treated with luteinizing hormone-releasing hormone (LHRH) analogs to achieve a maximum decrease in estradiol levels before initiating fulvestrant and to maintain a low estradiol level during therapy with fulvestrant.

• HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib, abemaciclib, or ribociclib.

The recommended dose of Fulvestrant Injection is 500 mg to be administered intramuscularly into the gluteal muscle once a month.

The most frequently reported adverse reactions in the clinical trials were injection site pain, nausea, bone pain, arthralgia, and vomiting (Table 4). Overall, the most frequently reported grade 3 or 4 laboratory abnormalities were increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST). Anemia was the most frequently reported grade 3 or 4 hematological adverse reaction.

For Administration:

The proper method of administration of Fulvestrant Injection for intramuscular use is described in the Dosage and Administration section of this full prescribing information.

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 removing needle shield and attempting to withdraw product.

3. Position holder with angle-locator perpendicular to skin surface in an area that accommodates the needle length. Align the angle-locator notch with the selected angle indicator. Depending on the angle indicator selected, hold the holder at a 60°, 90°, or 120° angle.

4. Forward. Listen for a click. Confirm that the safety shield has completely covered the needle before moving or tilting the holder. The needle is now locked to the Luer connector.

5. Complete insertion. Remove the safety shield from the needle by pulling it backward. For each syringe:

   a. Apply gentle pressure to the injection plunger; do not force injection.
   b. The proper method of administration of Fulvestrant Injection for intramuscular use is described in the Dosage and Administration section of this full prescribing information.

6. Remove needle from skin and allow the needle shield to cover the needle before completing the following instructions.

   a. Do not recap the needle. Remove the needle shield from the needle by pulling it backward.
   b. Discard used needle and injection device in accordance with local regulations. Do not re-use needles.

7. Apply gentle pressure to the injection plunger to aspirate any blood or other fluids left in the needle and syringe prior to withdrawal of drug product.

8. The injection site should be cleaned with an adequate amount of antiseptic solution from the syringe. Onset of action and duration of action: The onset of clinical benefit may occur within 1 to 2 months after initiating fulvestrant treatment, with a median duration of treatment of 10.8 months for fulvestrant plus palbociclib and 8 months for fulvestrant plus placebo in MONARCH 2. The median duration of treatment for fulvestrant plus abemaciclib was 14.9 months in CONFIRM and 8 months in MONARCH 2. The median duration of treatment for fulvestrant plus ribociclib was 10.2 months in CONFIRM and 8 months in MONARCH 2. The median duration of treatment for fulvestrant plus palbociclib was 10.8 months while the median duration of treatment for fulvestrant plus placebo was 8 months in MONARCH 2. The median duration of treatment for fulvestrant plus abemaciclib was 14.9 months.

9. To help avoid HIV (AIDS), HBV (Hepatitis), and other infectious diseases due to accidental needle-stick or needle-prick injuries, it is recommended that each SafetyGlide® Needle be used only once. Do not autoclave SafetyGlide® Needle before use.

10. Correction 30.04. 2019 07.54 Uhr

11. Correction 25.04. 2019 10.10 Uhr