



A Guide to Correct
**Preparation,
Mixing and
Administration
of Fensolvi**

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Mixing & Administration Roadmap

fensolvi[®]
(leuprolide acetate) for injectable
suspension

ROOM TEMP.
59-86° F

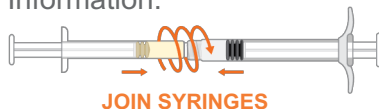


STEP 1

Preparation & Assembly

Allow the product to reach room temp. before using.

Connect the two syringes according to the steps in the Fensolvi[®] full Prescribing Information.



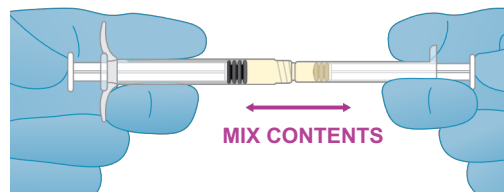
MIX FOR **45**
SECONDS



STEP 2

Mixing

Thoroughly mix the product for 45 seconds. Once mixed, healthcare professionals have 30 minutes to administer Fensolvi.



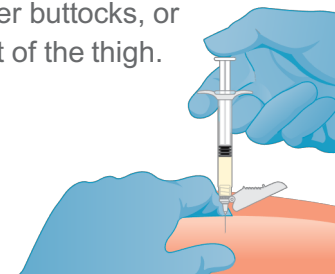
90°
ANGLE



STEP 3

Administration

Inject at a 90° angle into any appropriate subcutaneous tissue site on the body, such as the abdomen, upper buttocks, or front of the thigh.

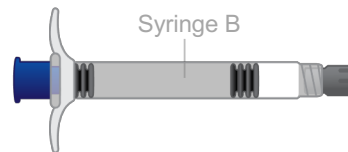
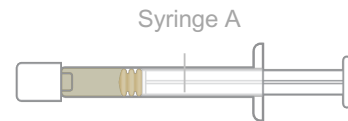


Fensolvi Packaging

Fensolvi is packaged in two trays containing:



- **One sterile Syringe A**, prefilled with the polymeric gel delivery system
- **One sterile Syringe B**, prefilled with leuprolide acetate powder
- **One long white plunger rod** for use with Syringe B
- **One sterile safety needle**
- **Desiccant pack(s)**



Handling and Preparation

IMPORTANT: Fensolvi must be brought to room temperature before mixing.

Once removed from refrigeration, Fensolvi can be stored in the original packaging for up to 8 weeks.

ROOM TEMP.
59-86° F

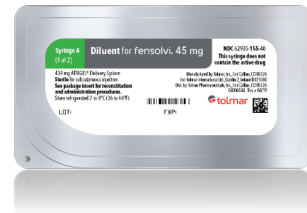
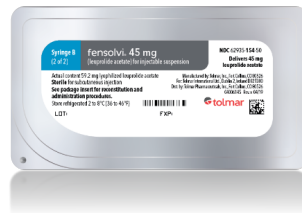


- Make sure patient is available, as Fensolvi **must be administered within 30 minutes** following mixing.
- Use aseptic technique including gloves for reconstitution and administration.

1

Assembly at room temperature

On a clean field open both trays, discard the desiccant packs from each package and ensure all contents are in place. You are now ready to assemble and mix Fensolvi.

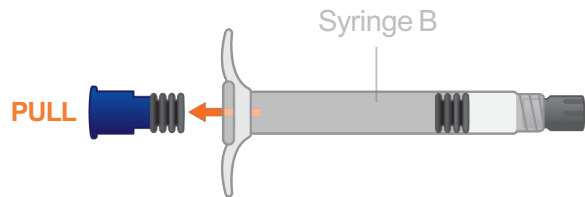


Assembly continued

2

Start with Syringe B: Pull out blue plunger

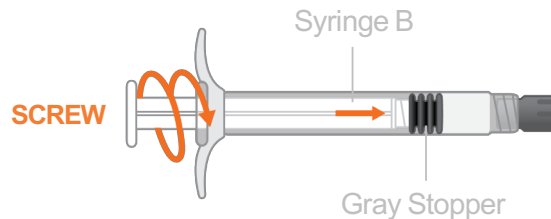
Pull out (do NOT unscrew) the short **blue plunger** rod with attached gray stopper from Syringe B and discard.



3

Insert the long white plunger rod from Syringe A package

Gently screw the white plunger rod into the remaining gray stopper in Syringe B.

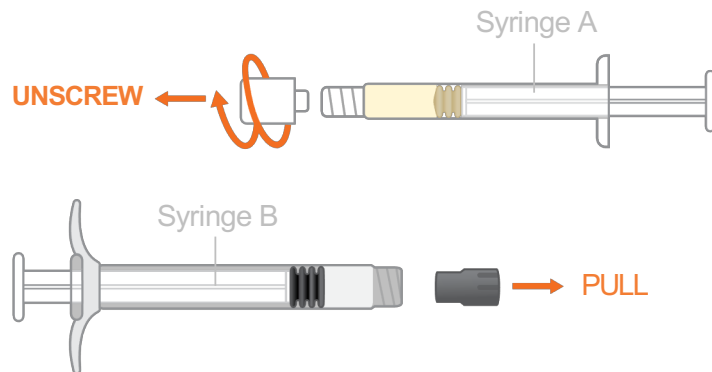


Assembly continued

4

Remove caps

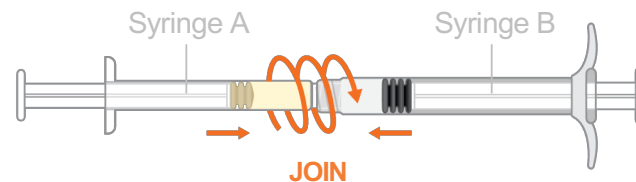
Remove and discard caps from both Syringe A and Syringe B.



5

Join the syringes

Join the two syringes together by pushing and gently screwing until secure.

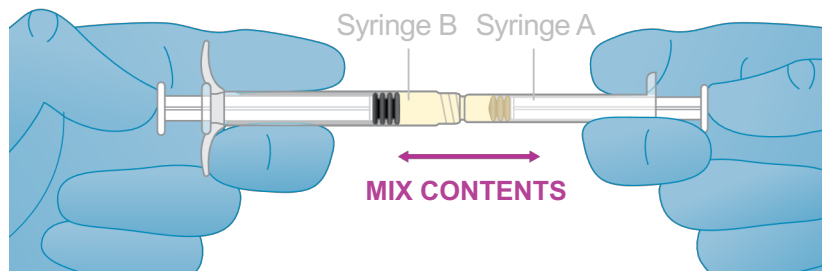


Mixing for 45 seconds

6

Mix contents

Inject the liquid contents of Syringe A into leuprolide acetate powder in Syringe B



- **Thoroughly mix the product for 45 seconds** by pushing the contents back and forth to obtain a uniform suspension.
- When thoroughly mixed, the suspension will appear pale yellow.

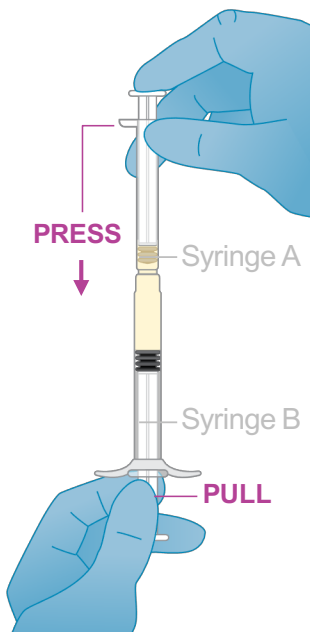
NOTE: Product must be mixed as described to ensure a uniform suspension is achieved. Shaking will not provide adequate mixing of the product.

Mixing steps continued

7

Draw all mixed product into Syringe B

Hold the syringes vertically (upright) with Syringe B on the bottom. The syringes should remain securely coupled. Draw all of the mixed product into Syringe B by depressing the Syringe A plunger and slightly withdrawing the Syringe B plunger.

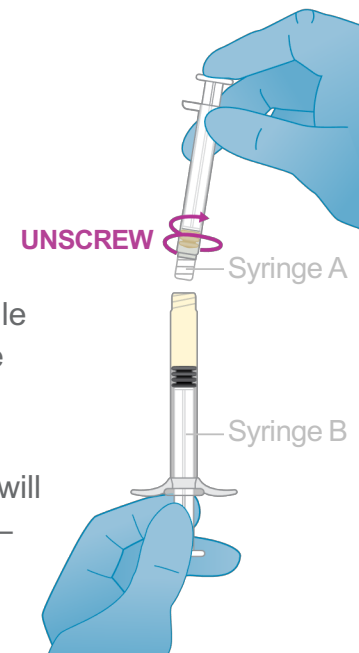


8

Uncouple syringes

Unscrew Syringe A to decouple the syringes while continuing to withdraw the Syringe B plunger.

NOTE: Small air bubbles will remain in the formulation – this is acceptable.

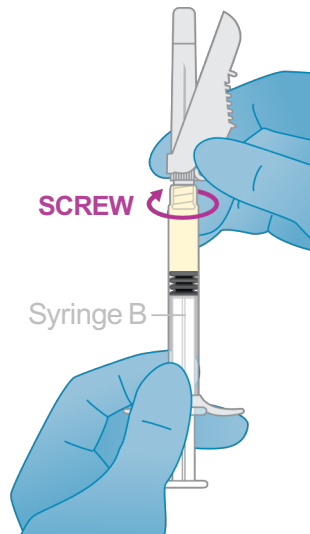


Mixing steps continued

9

Attach the sterile needle provided

Hold Syringe B upright. Hold back the white plunger on Syringe B to prevent loss of the product. Attach the safety needle cartridge. Gently screw clockwise with approximately a three-quarter turn until the needle is secure. **Do not overtighten.**



1. Move the safety sheath away from the needle.
2. Pull off the clear needle cartridge cover, immediately prior to administration.

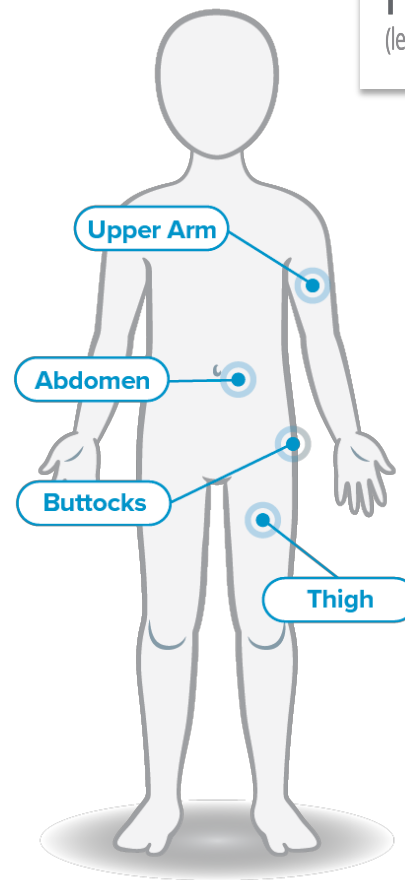
NOTE: Should the needle hub appear to be damaged, or leak, do not use the product. If the needle hub is damaged or leakage is observed, use a new Fensolvi carton.

Administration

10

Choosing an injection site

- Select an injection site on the upper buttocks, abdomen, or anywhere with adequate amounts of subcutaneous tissue that does not have excessive pigment, nodules, lesions, or hair. Avoid areas with brawny or fibrous subcutaneous tissue or locations that could be rubbed or compressed.
- Cleanse the area with an alcohol swab (not included).

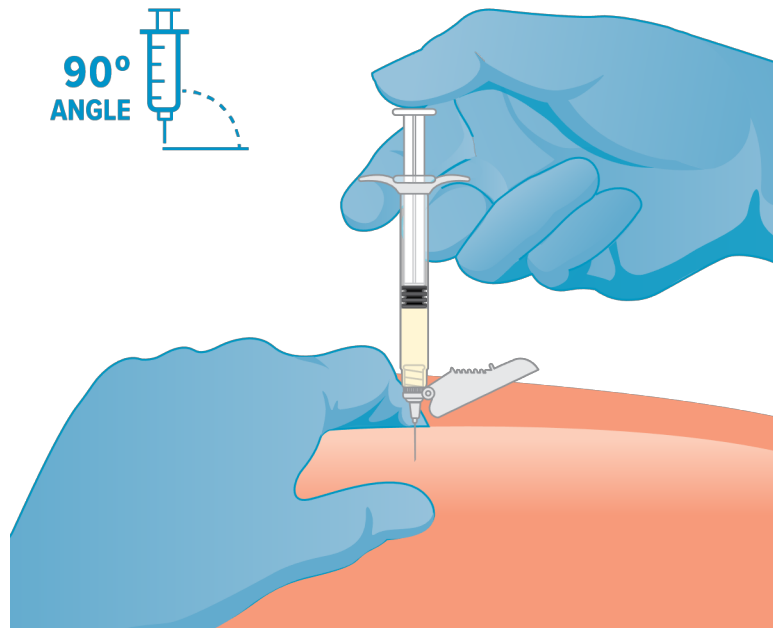


Administration continued

11

Administer injection

- Using the thumb and forefinger of your non-dominant hand, grasp an area of skin around the injection site.
- Using your dominant hand, insert needle quickly at a 90° angle, inject the drug using a slow, steady push. Withdraw the needle quickly at the same 90° angle.

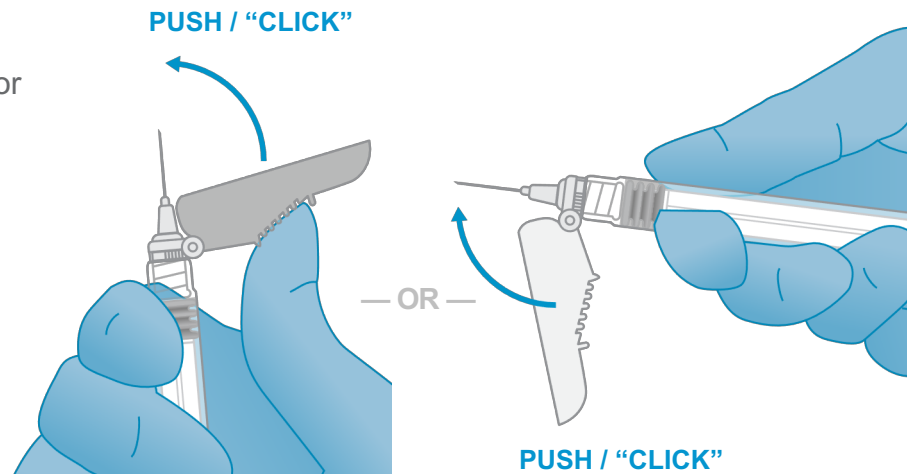


Administration continued

12

Activate needle safety shield

Activate the safety shield using a finger/thumb or flat surface and push until it completely covers the needle tip and locks into place. An audible and tactile “click” verifies a locked position. Check to confirm the safety sheath is fully engaged. **Discard all components safely in an appropriate biohazard container.**



IMPORTANT SAFETY INFORMATION

FENSOLVI (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls under the age of 8 or in boys under the age of 9.

FENSOLVI is contraindicated in individuals with hypersensitivity to any drug that is in the same class as FENSOLVI, in individuals who are allergic to any of the ingredients in FENSOLVI, or in individuals who are pregnant. FENSOLVI may cause fetal harm when administered to a pregnant patient.

During the first few weeks of treatment, increases in gonadotropins and sex steroids above baseline may result in an increase in signs and symptoms of puberty including vaginal bleeding in girls.

Psychiatric events have been reported in patients taking GnRH agonists. Events include emotional lability, such as crying, irritability, impatience, anger, and aggression. Patients should be monitored for development or worsening of psychiatric symptoms.

Convulsions have been observed in patients treated with GnRH agonists with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs.

The most common adverse events seen with FENSOLVI were: injection site pain, nasopharyngitis, pyrexia, headache, cough, abdominal pain, injection site erythema, nausea, constipation, vomiting, upper respiratory tract infection, bronchospasm, productive cough and hot flush.

Please click for full Prescribing Information for additional important safety information.

Reference: Fensolvi® (leuprolide acetate) for injectable suspension
45 mg prescribing information. Dublin 2, Ireland: Tolmar International, Ltd.; 2020.

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