ELIGARD®
(leuprorelin acetate)

INSTRUCTIONS FOR PREPARATION, RECONSTITUTION AND ADMINISTRATION

RECORDATI

eligard® leuprorelin acetate

PLEASE READ BEFORE PREPARATION
Please refer to the SmPC for full instructions and product information.

- ELIGARD should only be prepared, reconstituted and administered by a healthcare professional who is familiar with these procedures.
- Cases of handling errors which can occur during any step of the preparation process, and which could potentially result in lack of efficacy have been reported.

  Instructions for preparation, reconstitution and administration must be strictly followed. If the product is not prepared using the proper technique it should not be administered to any patient due to risk of lack of efficacy.
- As lack of efficacy may result from incorrect preparation, reconstitution, or administration, testosterone levels should be evaluated in cases of suspected or known handling errors.
- **Allow the product to come to room temperature by removing from the refrigerator approximately 30 minutes prior to use.**
- Administer ELIGARD subcutaneously immediately after mixing.

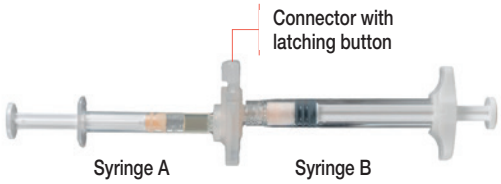
STEP 1

Open the tray by tearing off the foil from the corner of the tray. Empty the contents onto a clean surface.

After opening the tray, discard the desiccant pack included in the box.

Remove the pre-connected syringe system from the tray. Open the safety needle package by peeling back the paper tab.

Tray Contents: pre-connected syringe system

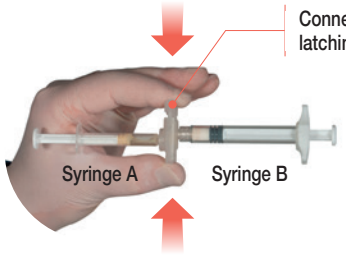


Under the Tray: safety needle and cap

STEP 2

Grasp the latching button on the connector with your finger and thumb and press until a snapping sound is heard. The two syringes will be lined up.

Do not bend the syringe system as this may cause leakage.

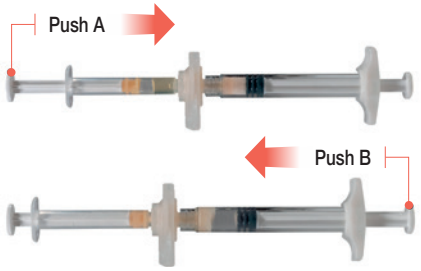


STEP 3

Holding the syringes in a horizontal position, transfer the liquid contents of Syringe A into the leuprorelin acetate powder contained in Syringe B.

Thoroughly mix the product for **60 cycles** by gently pushing the contents of both syringes back and forth between both syringes in a horizontal position to obtain a homogenous, viscous solution.

Note: A cycle is one push of the plunger for Syringe A and one push of the plunger for Syringe B.



When thoroughly mixed, the viscous solution will appear with a colour in the range of colourless to white to pale yellow (which could include shades of white to pale yellow).

After mixing proceed with the next step immediately as the product gets more viscous over time. Do not refrigerate the mixed product.

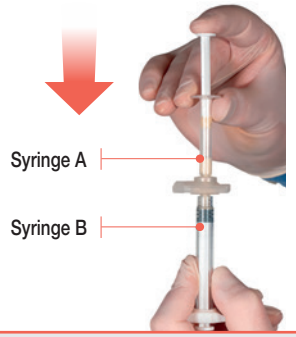
REPEAT 60X

STEP 4

After mixing, hold the syringes vertically with Syringe B on the bottom.

The syringes should remain securely coupled.

Then, draw the entire mixed product into Syringe B (short wide syringe) by pushing down the Syringe A plunger and slightly withdrawing the Syringe B plunger.



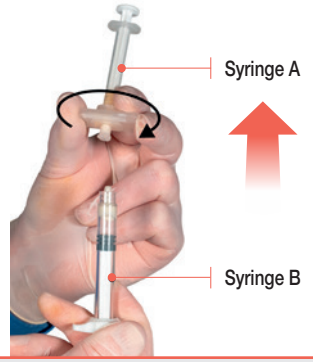
STEP 5

While ensuring Syringe A plunger is fully pushed down, hold the connector and unscrew it from Syringe B.

Syringe A will remain attached to the connector. Ensure that no product leaks out as the needle will then not secure properly when attached.

One large or a few small air bubbles may remain in the formulation - this is acceptable.

Don't purge the air bubbles from Syringe B at this stage, as some product may be lost.



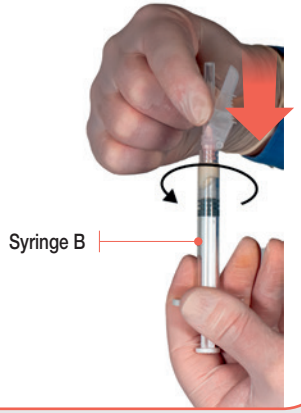
STEP 6

Hold Syringe B upright and hold back the white plunger to prevent loss of the product.

Secure the safety needle to Syringe B by holding the syringe and gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure.

Do not over tighten as this may cause cracking of the needle hub resulting in leakage of the product during injection.

Inject subcutaneously immediately after mixing.



STEP 7

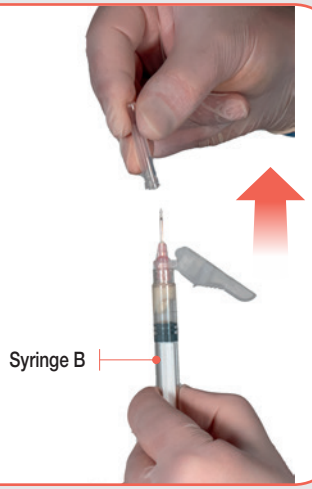
Move the safety shield away from the needle and pull off the protective needle cover immediately prior to administration.

IMPORTANT: Do not operate the safety needle mechanism before administration.

Should the needle hub appear to be damaged, or leak, the product should NOT be used.

The damaged needle should NOT be replaced and the product should NOT be injected.

In the event of damage to the needle hub, use another ELIGARD kit.



REPORTING SUSPECTED ADVERSE REACTIONS

- Full prescribing information for Eligard can be obtained at www.hpra.ie and www.medicines.ie.
- All cases of incorrect storage, preparation, reconstitution, and administration of ELIGARD or any other adverse reactions should be reported to Recordati directly and to the Health Products RegulatoryAuthority (HPRA).
- Healthcare professionals are asked to report any suspected adverse reactions via:

- **HPRA Pharmacovigilance website**: www.hpra.ie
- **Recordati Ireland Limited:**
  Tel.: 021 437 9400
  Email: medinfo@recordati.co.uk

STEP 8

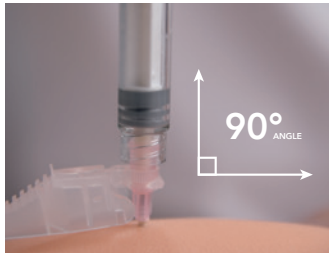
Prior to administration, purge any large air bubbles from Syringe B. Administer the product subcutaneously whilst keeping the safety shield away from the needle.

ADMINISTRATION PROCEDURE:

- Select an injection site on the abdomen, upper buttocks, or another location with adequate amounts of subcutaneous tissue that does not have excessive pigment, nodules, lesions, or hair and has not recently been used.
- Cleanse the injection-site area with an alcohol swab (not enclosed).
- Using the thumb and forefinger, grab and bunch the area of skin around the injection site.
- Using your dominant hand, insert the needle quickly at a 90° angle to the skin surface.

  The depth of penetration will depend on the amount and fullness of the subcutaneous tissue and the length of the needle. After the needle is inserted, release the skin.
- Inject the drug using a slow, steady push and press down on the plunger until the syringe is empty.

  Please ensure that the full amount of the product in Syringe B is injected before removing the needle.
- Withdraw the needle quickly at the same 90° angle used for insertion while maintaining pressure on the plunger.

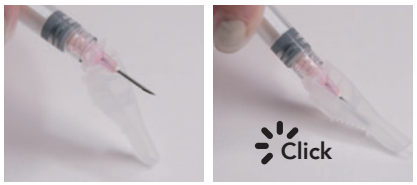


STEP 9

Immediately following the withdrawal of the needle, activate the safety shield using a finger/thumb or flat surface and push until it completely covers the needle tip and locks into place.

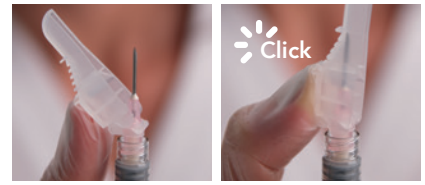
You should hear an audible “click” when locked into position.

Closure on a flat surface



OR

Closure with your thumb



Once safety shield is locked, immediately dispose of the needle and syringe in an approved sharps container.