

**PLEASE READ BEFORE RECONSTITUTION**

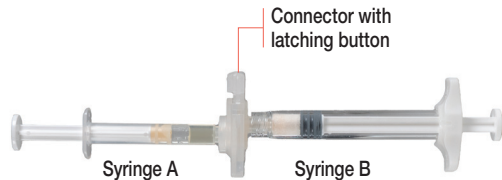
Please refer to the SmPC for full instructions and product information.

- ELIGARD should be prepared, reconstituted and administered only by healthcare professionals who are 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 reconstitution and administration must be strictly followed.
- 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.**
- Once reconstituted: use immediately, as the viscosity of the solution increases with time.

**STEP 1**

On a clean field, open the tray by tearing off the foil from the corners to remove the contents. Discard the desiccant pouch. 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

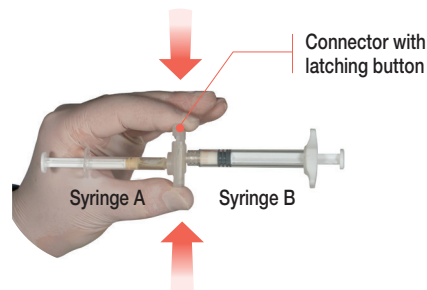


Under the Tray: safety needle and cap



**STEP 2**

Grasp the latching button on the connector with your finger and thumb and press until you hear a snapping sound. The two syringes will be lined up. No particular orientation of the syringe system is required to activate the connector. Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).



**STEP 3**

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

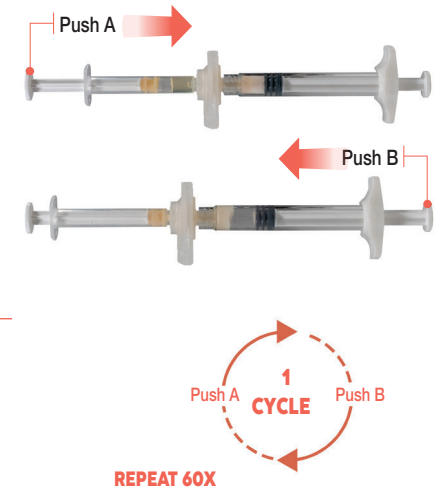
Thoroughly mix the product for 60 cycles by gently pushing the contents of both syringes back and forth between both syringes (a cycle is one push of the plunger for Syringe A and one push of the plunger for Syringe B) in a horizontal position to obtain a homogenous, viscous solution.

Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).

Product must be mixed as described; shaking WILL NOT provide adequate mixing of the product.

**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.**

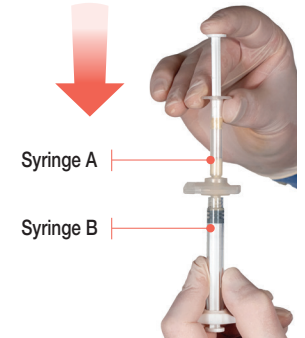


**STEP 4**

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 by pushing down the Syringe A plunger and slightly withdrawing the Syringe B plunger.



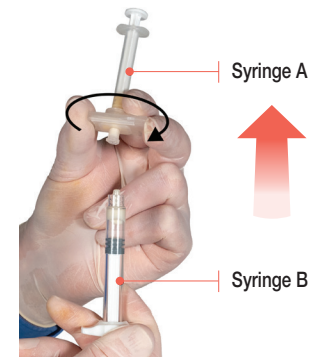
**STEP 5**

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.

**Please do not purge the air bubbles from Syringe B at this stage as product may be lost!**



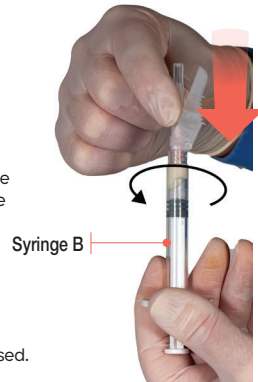
## STEP 6

- 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. The safety shield may also be damaged if the needle is screwed with too much force.

Should the needle hub crack, appear to be damaged, or have any leakage, the product should not be used. The damaged needle should not be substituted/replaced and the product should not be injected. The entire product should be disposed of securely.

In the event of damage to the needle hub, a new replacement product should be used.



## 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:

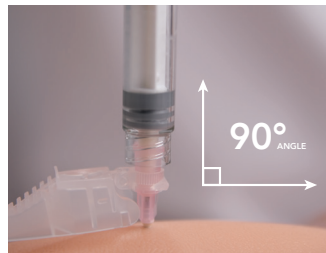
- Select an injection site on the abdomen, upper buttocks, or another location with adequate amounts of subcutaneous tissue that does not have excessive pigment, nodules, lesions, or hair and has not recently been used.
- Cleanse the injection-site area with an alcohol swab (not enclosed).
- Using the 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 7

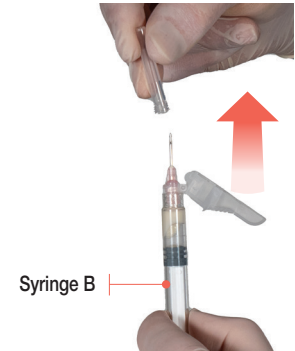
Move the safety shield away from the needle and pull off the protective needle cover immediately prior to administration.

**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.**



## STEP 9

After injection, lock the safety shield using any of the activation methods listed below.

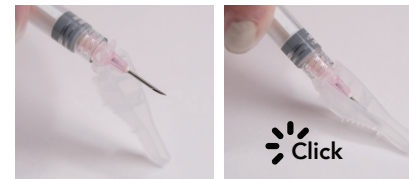
### 1. Closure on a flat surface

Press the safety shield, lever side down, onto a flat surface to cover the needle and lock the shield. Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.

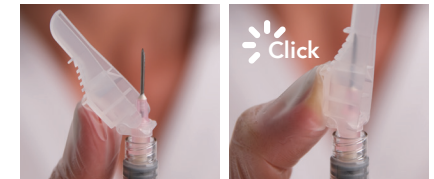
### 2. Closure with your thumb

Placing your thumb on the safety shield, cover the needle tip and lock the shield. Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.

### Closure on a flat surface



### Closure with your thumb



OR

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

## REPORTING ADVERSE EVENTS

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il>

Additionally, you should also report to Kamada Ltd. to email address: [pharmacovigilance@kamada.com](mailto:pharmacovigilance@kamada.com)