Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ELIGARD 22.5 mg powder and solvent for solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One prefilled syringe with powder for solution for injection contains 22.5 mg leuprorelin acetate, equivalent to 20.87 mg leuprorelin.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

Product imported from Czech Republic:

Powder (Syringe B): Pre-filled syringe with a white to off-white powder.

Solvent (Syringe A): Pre-filled syringe with a clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

As per PA0812/005/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0812/005/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Solvent (syringe A): Poly (DL-lactic-co-glycolic-acid) (75:25)
N-Methylpyrrolidone

Powder (syringe B): None

6.2 Incompatibilities

The leuprorelin present in syringe B must only be mixed with the solvent in syringe A and must not be mixed with other medicinal products.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the tray and outer package of the product on the market in the country of origin.

Once the product has been removed from the refrigerator, it may be stored in the original packaging at room temperature (below 25°C) for up to four weeks.

After first opening of the tray, the powder and solvent for solution for injection are to be immediately reconstituted and administered to the patient.

Once reconstituted: use immediately, as the viscosity of the solution increases with time.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C); in the original package in order to protect from moisture. This product must be at room temperature prior to injection. Remove from the refrigerator approximately 30 minutes before use. Once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to four weeks.

6.5 Nature and contents of container

A pre--connected syringe system consisting of:

- one pre-filled syringe containing powder (Syringe B)
- one pre-filled syringe containing solvent (Syringe A)
- a connector with latching button for Syringe A and B.

Syringe A has a plunger tip. Syringe B has a plunger tip.

The following pack sizes are available:

- A kit consisting of a thermoformed tray and a 20-gauge sterile needle in a cardboard carton. The tray contains one pre-connected syringe system and a desiccant pouch.

6.6 Special precautions for disposal and other handling

Allow the product to come to room temperature by removing from the refrigerator approximately 30 minutes prior to use.
Please prepare the patient for injection first, followed by the preparation of the product, using the instructions below.
If the product is not prepared using the proper technique, it should not be administered, as lack of clinical efficacy may occur due to incorrect reconstitution of the product.

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 (Figure 1.1) from the tray. Open the safety needle package (Figure 1.2) by peeling back the paper tab. **Note:** Syringe A and Syringe B should not be lined-up yet.

Figure 1.1
Tray Contents: pre-connected syringe system

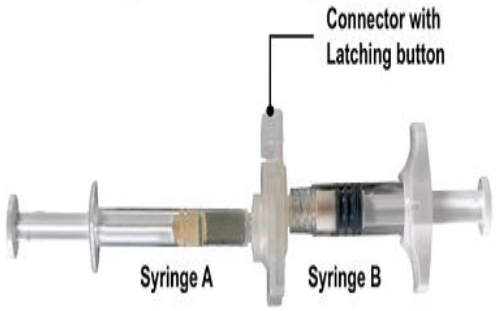


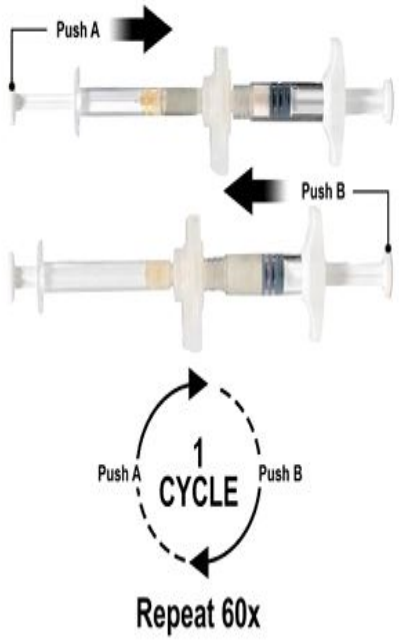
Figure 1.2
Under the Tray: safety needle and cap

Step 2
Grasp the latching button on the connector with your finger and thumb and press (Figure 2) 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).

Figure 2

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 (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 (Figure 3). Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).

Figure 3



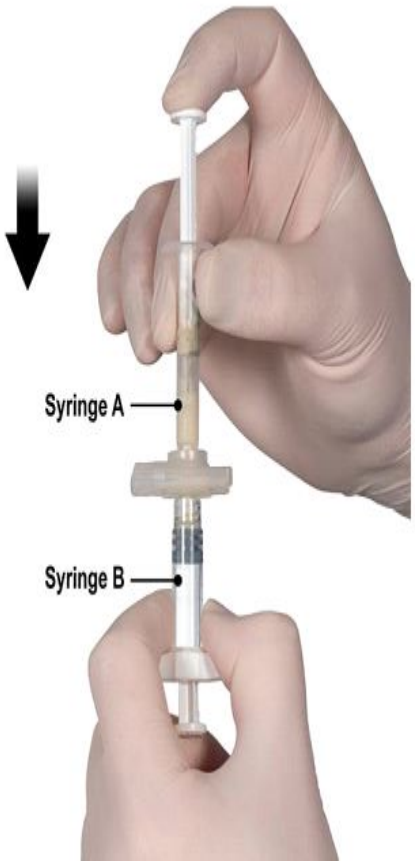
When thoroughly mixed, the viscous solution will appear with a colour in the range of colourless to white to pale yellow (which could include shades of white to pale yellow).

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

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

Step 4
After mixing, hold the syringes vertically with Syringe B on the bottom. The syringes should remain securely coupled. 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 (Figure 4).

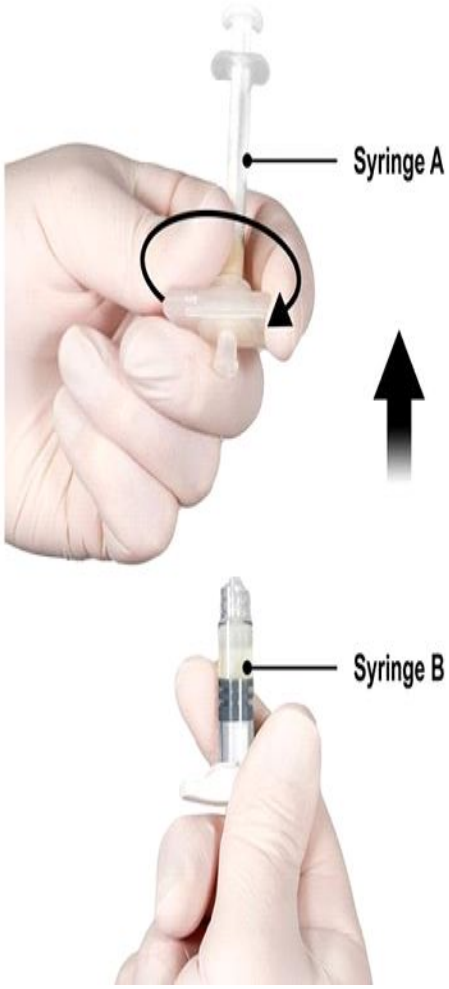
Figure 4



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 (Figure 5). Ensure that no product leaks out as the needle will then not secure properly when attached.

Please note: 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!**

Figure 5



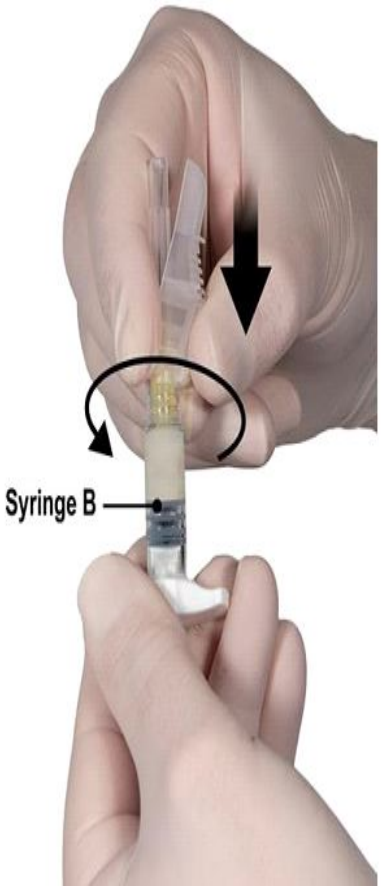
Step 6

- 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 (Figure 6). 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.

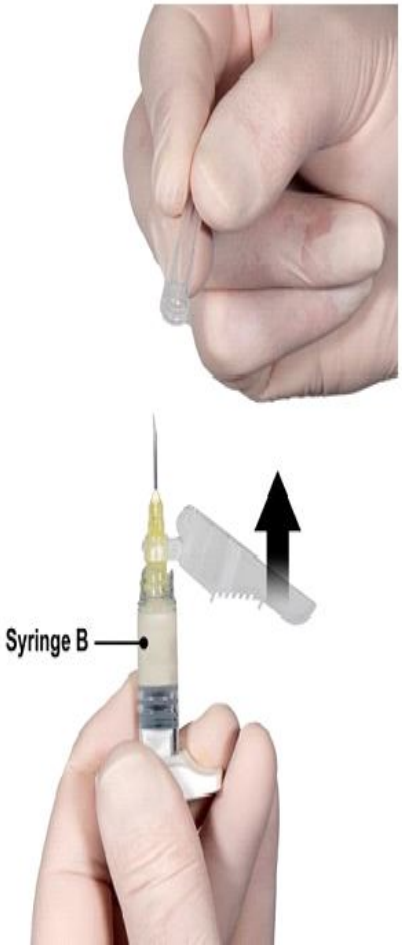
In the event of damage to the needle hub, a new replacement product should be used.

Figure 6



Step 7
Move the safety shield away from the needle and pull off the protective needle cover prior to administration (Figure 7).
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.

Figure 7



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.

Figure 8

Step 9
After injection, lock the safety shield using any of the activation methods listed below.

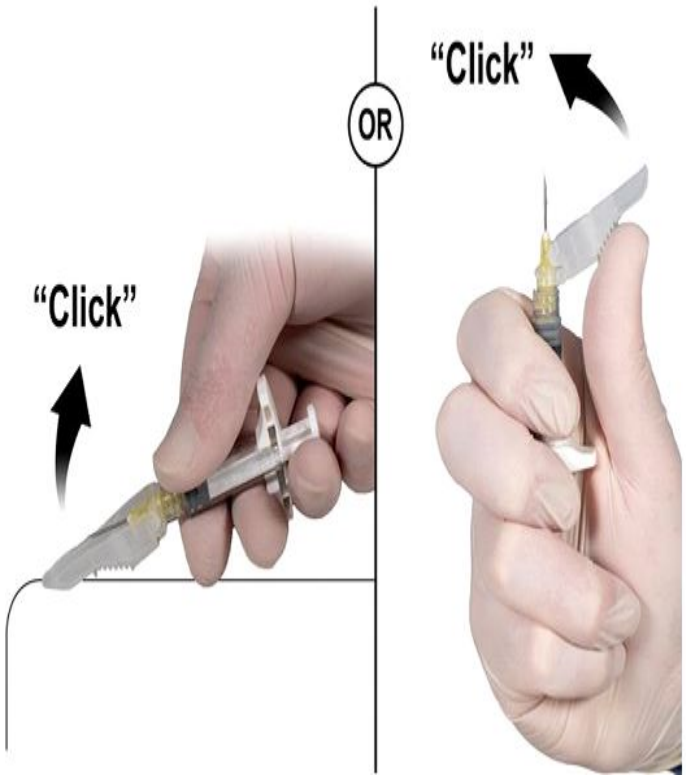
1. Closure on a flat surface
Press the safety shield, lever side down, onto a flat surface (Figure 9a) to cover the needle and lock the shield. Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.

2. Closure with your thumb
Placing your thumb on the safety shield (Figure 9b), cover the needle tip and lock the shield.

Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.

Figure 9a
Closure on a flat surface

Figure 9b
Closure with your thumb



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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/511/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd January 2025

10 DATE OF REVISION OF THE TEXT