ELIGARD®
leuprorelin acetate

FOR HEALTHCARE PROFESSIONALS ONLY.

ELIGARD® must be administered by a healthcare practitioner.

A GUIDE TO

Preparation, mixing, and injection of ELIGARD®

(LEUPRORELIN ACETATE) MODIFIED RELEASE INJECTION SYRINGE, available in a single-use kit.

For the palliative treatment of advanced prostate cancer and high-risk localised and locally advanced hormone-dependent prostate cancer in combination with radiotherapy. ELIGARD® 7.5 mg 1 month, ELIGARD® 22.5 mg 3 month, ELIGARD® 30 mg 4 month, and ELIGARD® 45 mg 6 month.[1]

For the treatment of children 2 years of age and older with central precocious puberty. ELIGARD® 45 mg 6 month.[1]

ELIGARD® leuprorelin acetate

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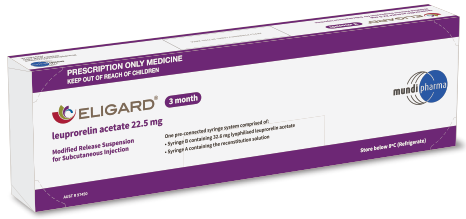
ELIGARD® dose range[1]

ELIGARD® for Prostate Cancer

For the palliative treatment of advanced prostate cancer and high-risk localised and locally advanced hormone-dependent prostate cancer in combination with radiotherapy.[1]

1 month | 7.5 mg
5 repeats

12 injections per year



3 month | 22.5 mg
1 repeat

4 injections per year

4 month | 30 mg
1 repeat

3 injections per year

6 month | 45 mg
0 repeats

2 injections per year

ELIGARD® for Central Precocious Puberty

For the treatment of children 2 years of age and older with central precocious puberty (CPP).[1]

6 month | 45 mg
0 repeats

2 injections per year

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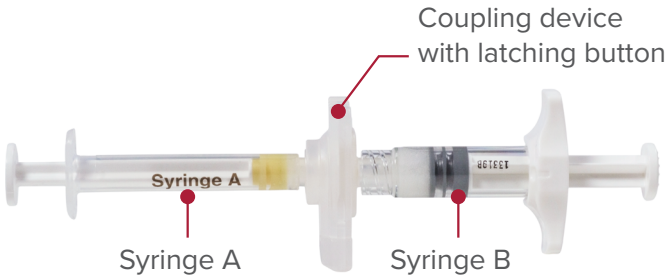
ELIGARD® packaging[1]

ELIGARD® is packaged in a carton containing:

SYRINGE TRAY

Contains the ELIGARD® pre-connected syringe system, which is composed of:

- **Syringe A** (pre-filled with the Atrigel® Delivery System)
- **Syringe B** (pre-filled with lyophilised leuprorelin acetate powder)
- **Coupling device**
- **Desiccant pack**



SAFETY NEEDLE

The sterile safety needle and cap is **UNDER the tray**

PACKAGE INSERT

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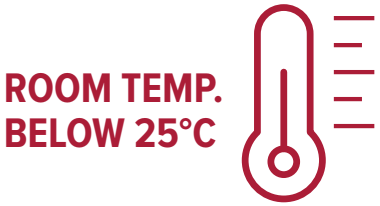
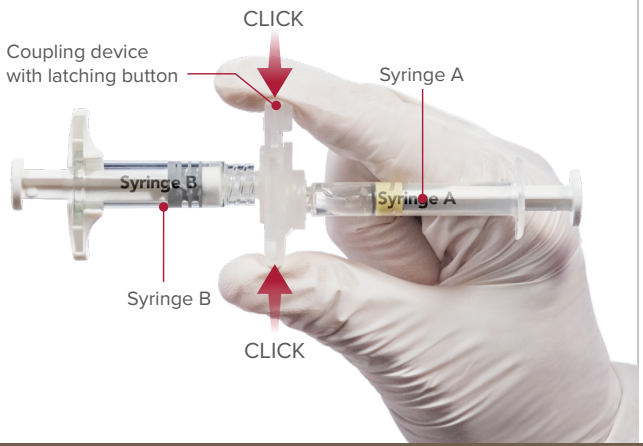
Administration summary[1]

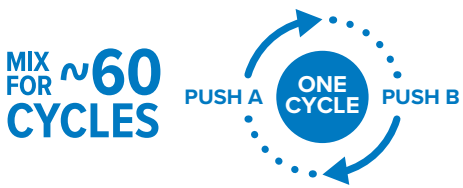


STEP 1

Preparation

Allow the product to reach room temperature at least 30 minutes before mixing. Remove the pre-connected syringe system from the tray.

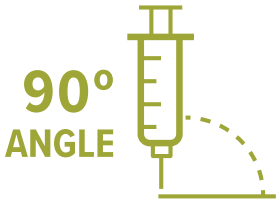




STEP 2

Mixing

Thoroughly mix the product for at least 60 cycles. **A cycle is one push of the Syringe A plunger and one push of the Syringe B plunger.** Once mixed, ELIGARD® must be administered within 30 minutes.



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. **ELIGARD® should not be injected in the arm.**

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Administration roadmap[1]

ROOM TEMP. BELOW 25°C

MIX FOR ≈60 CYCLES

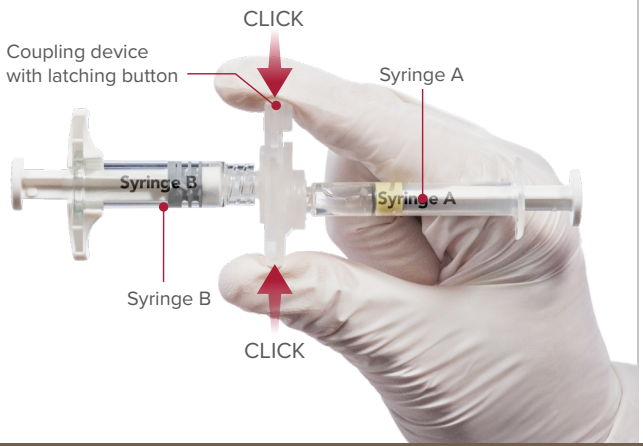
PUSH A — ONE CYCLE — PUSH B

90° ANGLE

STEP 1

Preparation

1. Open the ELIGARD® carton
2. Align the two syringes — 'CLICK'



STEP 2

Mixing

3. Mix contents for ≥60 cycles
   - A cycle is one push of the Syringe A plunger and one push of the Syringe B plunger
4. Draw all mixed product into Syringe B
5. Uncouple the syringes

STEP 3

Administration

6. Aseptically attach the sterile needle provided
7. Choose a subcutaneous injection site
8. Inject ELIGARD®
9. Release the needle safety shield

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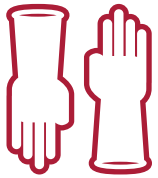
Preparation[1]

ROOM TEMP. BELOW 25°C

IMPORTANT: ELIGARD® must be brought to room temperature at least 30 minutes before mixing.

ELIGARD® should be stored below 8°C (refrigerated). Before reconstitution, the patient may store ELIGARD® below 25°C in intact packaging for up to 8 weeks.

Make sure patient is available, as ELIGARD® must be administered within 30 minutes following mixing.



The use of gloves is recommended during mixing and administration.

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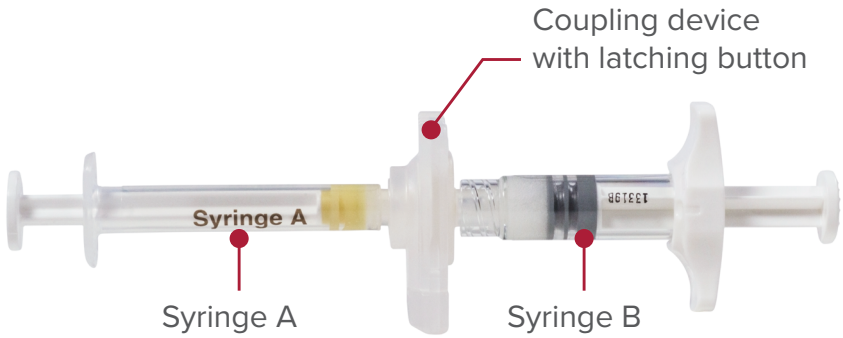
Preparation continued[1]

1 Open the ELIGARD® carton

- On a clean field, open the syringe tray by tearing off the foil from the corner and remove the contents. Discard the desiccant pack. Remove the pre-connected syringe system from the tray.
- Open the sterile safety needle package by peeling back the paper tab.

Syringe A and Syringe B should not be lined-up yet.

The product should only be administered with the co-packaged, sterile safety needle.



Under the tray

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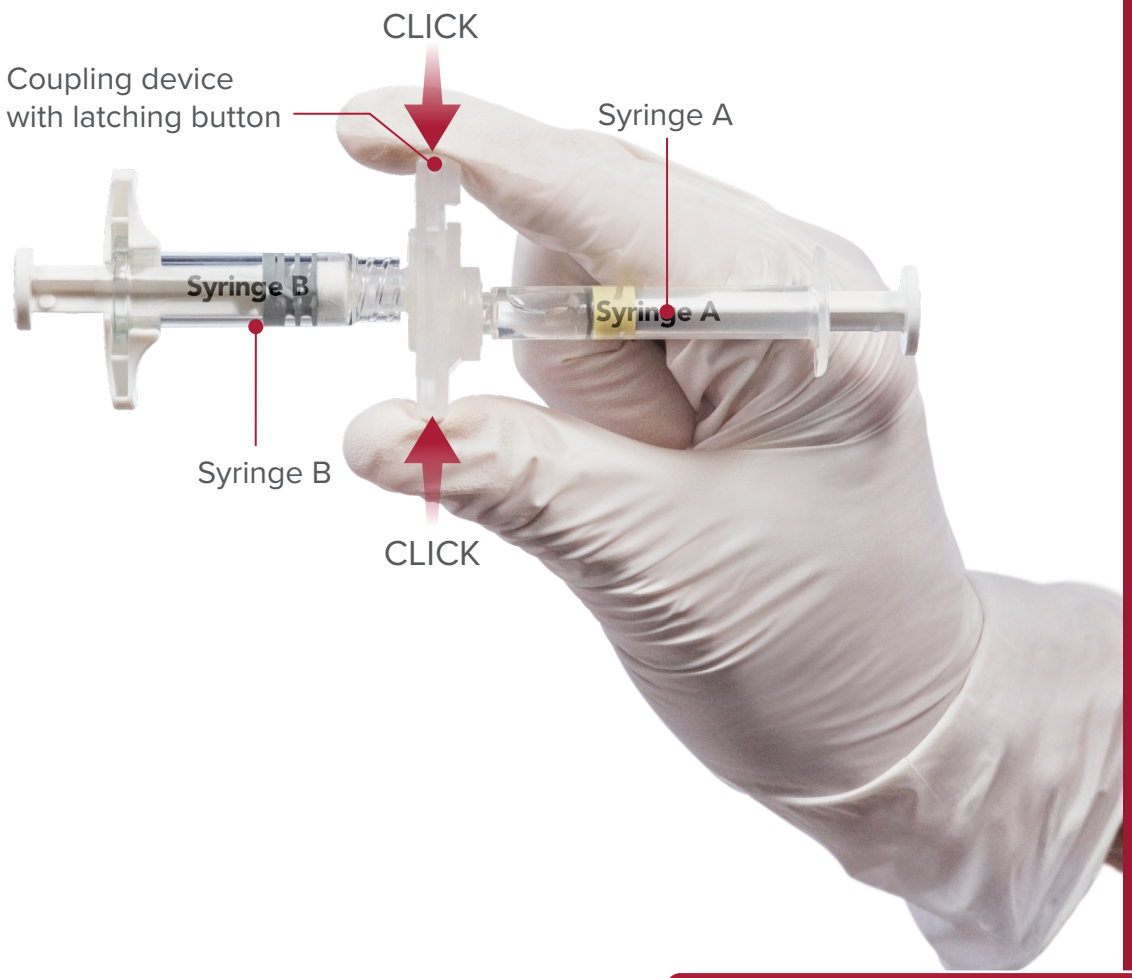
Preparation continued[1]

2 Align the two syringes — 'CLICK'

- Grasp the latching button on the coupling device with your finger and thumb, and **press until you hear a 'CLICK'** — the two syringes will be aligned.
- **Do not bend the pre-connected syringe system.**

ELIGARD® is now ready to mix.



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Mixing[1]

3 Mix contents for ≥60 cycles

- Holding the syringes in a horizontal position, transfer the liquid contents of **Syringe A** into the leuprorelin powder contained in **Syringe B.**
- Mix thoroughly by pushing the contents back and forth between the syringes for **at least 60 cycles.**

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

- This will mix ELIGARD® for use and activate the Atrigel® delivery technology.

NOTE: The initial 10–20 cycles may take slightly more effort than the remaining cycles during mixing. Product must be mixed as described; shaking will NOT provide adequate mixing. Do not bend.

When thoroughly mixed, the suspension will appear light tan to tan (ELIGARD® 7.5 mg) or colourless to pale yellow (ELIGARD® 22.5 mg, 30 mg, and 45 mg).

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Mixing continued[1]

4 Draw all mixed product into Syringe B

- After mixing, hold the syringes vertically (upright) with Syringe B (wide syringe) on the bottom. The syringes should remain securely coupled.
- Draw the entire mixed product into Syringe B (wide syringe) by depressing the Syringe A plunger and slightly withdrawing the Syringe B plunger.

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Mixing continued[1]

5 Uncouple the syringes

- While continuing to push down on the Syringe A plunger, **hold the coupling device and unscrew Syringe B.**
  - This will disconnect Syringe B from the coupling device.
  - Syringe A will remain attached to the coupling device.

Small air bubbles will remain in the formulation – this is acceptable. Do not purge the air bubbles from Syringe B as product may be lost.

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Injection[1]

6 Aseptically attach the sterile needle provided

- Continue to hold Syringe B upright with the open end at the top.
- Holding the needle in its cap, attach it by **gently screwing clockwise until the needle is secure** (approximately three-quarter turn).
  - **DO NOT OVERTIGHTEN.**
- Move the safety shield away from the needle and towards the syringe. Pull off the cap immediately prior to administration.

IMPORTANT: DO NOT OVERTIGHTEN, as the needle hub may become damaged, which could result in leakage of the product during injection. Should the needle hub appear to be damaged, or leak, the product should NOT be used. The damaged safety needle and cap should NOT be replaced, and the product should NOT be injected. In the event of damage to the needle hub, use a new replacement ELIGARD® carton.

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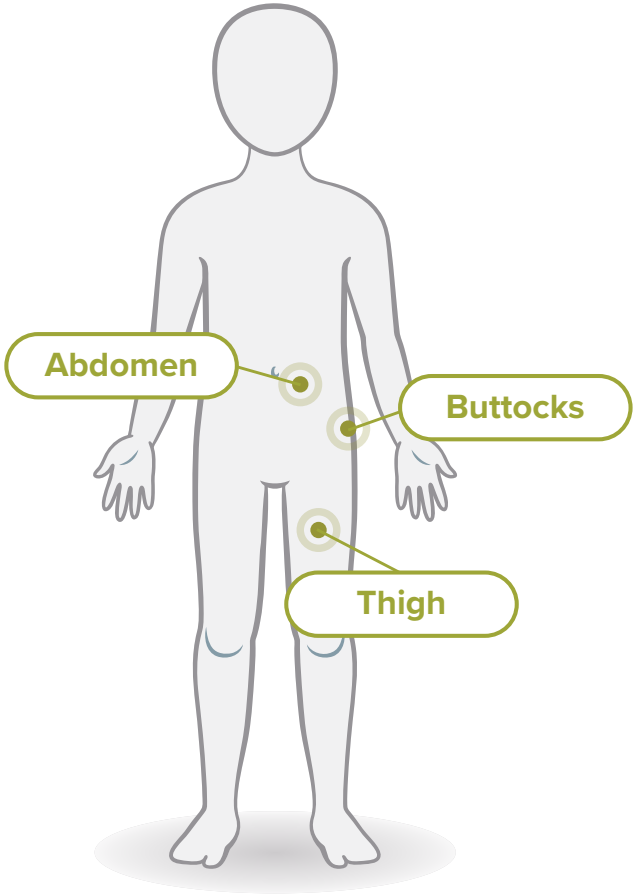
Injection continued[1]

7 Choose an injection site

Select an appropriate subcutaneous 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.
- **Do NOT inject in the arm.**

Cleanse the area with an alcohol swab (not included).



Vary the injection site periodically

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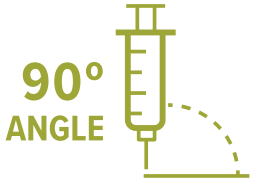
Injection continued[1]

8 Inject ELIGARD®

- 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 medication using a **slow, steady push,** and press down on the plunger until the syringe is empty, before removing the needle at the same **90° angle.**
  - Extra volume will remain in the needle hub.



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Injection continued[1]

9 Release the needle safety shield

- Immediately following the withdrawal of the needle, engage 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 sharps container.

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Preparation, mixing, and injection FAQs[1,2]

Contents page

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Preparation, mixing, and injection FAQs[1,2]

Contents page *continued*

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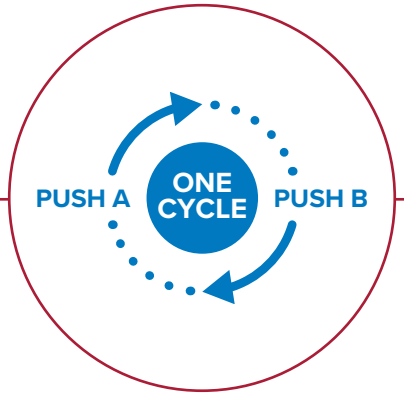
What is a cycle?

I am used to counting seconds.

- A cycle is one push of the Syringe A plunger AND one push of the Syringe B plunger with your thumbs.[2]



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What if I do not mix for 60 complete cycles?

The product will **not be fully reconstituted,** and you may not achieve the efficacy expected.

What should I do if I forgot what number of cycles I am on (interrupted, etc.)?

- Start counting over from the last number you recall or from the beginning. The device is designed to deliver the correct dose following 60 complete cycles.
- It is **acceptable to mix for more than 60 cycles.** Less than 60 cycles will result in the product not being fully reconstituted and you may not achieve the efficacy expected.

CLICK here for some tips

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Is there a time I can substitute for the 60 cycles instead of counting?

It will be very difficult to count in my clinic, too many distractions, etc.

Mundipharma does **not recommend substituting time for 60 cycles** as the product may not be fully reconstituted and you may not achieve the efficacy expected.[3]

CLICK here for some tips

The pre-connected syringe system is a little harder to push back and forth than the classic design, and the pressure required to mix seems to change (more needed at start)—why is that?

- The pre-connected syringe system is different with the addition of the coupling device; therefore, the initial **10–20 cycles may take slightly more effort** during mixing.
- Start with slow/partial plunger rod compressions to get the powder into suspension (5–10 cycles) and then use complete plunger rod (syringe) compressions for each syringe.

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Do you have any tips to make sure I count to 60 cycles?

Remember that one cycle is two thumb pushes – **back and forth** (120 single thumb pushes in total).

Counting **out loud** may prevent you from getting distracted.

Count each time you push with your dominant hand/thumb.
Only count on your dominant hand.

Count in **2 sets of 30.**

Minimise distractions before mixing so that you are unlikely to be interrupted.

Do not engage in conversation while mixing.

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Will I know when it's fully mixed?

No. A change in colour **does not indicate** a complete mix.

Will I see powder if it is not fully mixed?

Not necessarily, and not seeing powder is **not an indication** of a complete mix.

Why have you changed from 45 seconds to 60 cycles?

- The pre-connected syringe system was designed to **simplify the preparation process** and eliminate four steps from the classic ELIGARD® assembly.
- To achieve efficacy with the pre-connected syringe system, 60 cycles are required to reconstitute the product sufficiently.
- 45 seconds is **not equivalent** to 60 cycles.
- The product **will not be fully reconstituted** if you do not mix 60 cycles, and you may not achieve the efficacy expected.

How long will 60 cycles take? It seems to take longer to mix than the classic version.

- The time in which it takes to complete 60 cycles **can vary from one person to another**.
- Time has been saved with the elimination of steps so do not try to rush the 60 cycles.
- **Even and steady mixing is the goal**. Vigorous mixing and/or too much pressure may cause the coupling device to leak.

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See Important Safety Information at the end of this booklet and refer to the full Product Information HERE

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Why can't I use 45 seconds instead?

- The pre-connected syringe system was designed to **simplify** the preparation process, eliminating four steps from the classic ELIGARD® assembly.
- While the classic system effectively reconstituted the product with 45 seconds of mixing, the pre-connected syringe system **requires 60 full cycles** to achieve proper reconstitution.[3]
  - A cycle is one push of the Syringe A plunger and one push of the Syringe B plunger.[2]
- Mixing for 60 cycles **activates the Atrigel®** and reconstitutes ELIGARD® for use.[2]
- 45 seconds is **not equivalent** to 60 cycles, and the time in which it takes to complete 60 mixing cycles can vary from one person to another.
- If the product is not mixed for the full 60 cycles, **it will not be fully reconstituted**, which may impact its intended preparation and use.
- Since the pre-connected syringe system differs from the classic system, following the updated mixing instructions is **essential**.

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I didn't hear a click when I depressed the button on the coupling device. Is this a problem?

As long as the syringes are **visibly aligned** for mixing, that is OK.

Is the amount of medication delivered through the needle the same?

Yes! The contents of each syringe were adjusted for the pre-connected syringe system to ensure that the **same dose** of product is administered.[1]

Is there medication left in Syringe A or the coupling device after mixing?

- **Yes,** there is small amount of medication left in Syringe A and the coupling device.
- This is not different from the classic ELIGARD®, which also retains a small amount of medication in Syringe A after mixing and disconnection.
- The amount injected though **is the same.**

What if the syringes get bent during the connecting process? Can I bend it back and use it?

No. Please do not use the product.

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How do I pull back on Syringe B plunger when unscrewing the device after mixing?

- While continuing to push down on the Syringe A plunger, hold the coupling device and unscrew Syringe B.[2]
  - This will disconnect Syringe B from the coupling device.[2]
  - Syringe A will remain attached to the coupling device.[2]

NOTE: Small air bubbles will remain in the formulation (this is acceptable). Do not purge the air bubbles from Syringe B as product may be lost.

What if I unscrew the device before mixing? Can I join it again then mix?

No. Do not unscrew the device before mixing, as this compromises the sterility and integrity of the device.

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I pushed the coupling device accidentally and I wasn't ready to mix or inject the product. How do I store the product now?

- As you have unsealed the tray and pushed the coupling device, the product is considered opened and should be used.
- If you are unable to mix and administer **within 30 minutes**, please **do not use the product**.

Does the pre-connected syringe system change how I discard the product?

No. Any unused ELIGARD® should be disposed in a safe manner by a healthcare professional.[1,2]

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Have the storage conditions changed for the pre-connected syringe system (e.g., is 8 weeks at room temperature allowed)?

- The product storage requirements are **unchanged**.
- ELIGARD® should be stored below 8°C (refrigerated).[1]
- Before reconstitution, the patient may store ELIGARD® below 25°C in intact packaging for a period of 8 weeks.[1]

I accidentally pushed both syringes at once and product filled the coupling device. What should I do?

The product has been compromised and **should not be used**.

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What will happen if I push the powder syringe into the liquid syringe first (instead of liquid into powder)?

- The powder will compact and not transfer to the liquid syringe.
- It is always recommended to push the **liquid into the powder as the first step** to ensure thorough mixing of the product.
- Improper mixing could result in clogging of the connecting device in the pre-connected syringe product, clogging of the needle, and improper dosing.
- If the full product is not reconstituted, **do not use.**

What will happen if I push a syringe's content before clicking the coupling device?

- The coupling device **must be engaged** before correct mixing.
- If the liquid syringe is pushed first, there will be resistance.
- If the pressure on the plunger is increased, the seal will be compromised and the polymer will fill the cavity of the connector rendering the **product unusable**.
- If the powder syringe is pushed first, it will compress the product.
- **Do not use the device** if any syringe has been pushed before the coupling device was engaged.

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Why does the leuprorelin powder in Syringe B and/or stopper on Syringe A look tan or darker than in the classic kit?

- Because the 2-syringe system is pre-connected, both Syringe A and Syringe B are irradiated in the sterilisation process which **may cause a colour change**.
- This colour does not cause any harm or change to the product's efficacy.

My thumbs get tired, my thumbs hurt, my hands hurt. Any suggestions?

- Take a break after 20 or 30 cycles, flex and stretch the hands. And start again. No need to rush.
- Flip the syringes around to push Syringe A using the alternate thumb.
- Move cycle mixing to the thenar eminence area of the palm (fleshy part of thumb) for some of the 60 cycles.

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This updated process may be confusing for my injecting staff. Can I just use 60 cycles for my classic ELIGARD®?

- The minimum mixing time for reconstituting classic ELIGARD® is 45 seconds.
- 60 cycles could be used in place of 45 seconds for classic ELIGARD® if you wish to have all your injecting staff use the same process.
- **Please note, you cannot use 45 seconds of mixing for the ELIGARD® pre-connected syringe system.**
- 60 cycles was determined to be necessary to reconstitute the product sufficiently in the pre-connected syringe system.[2,3]
- 45 seconds is not equivalent to 60 cycles.
- The product will not be fully reconstituted if you do not mix 60 cycles, and may impact its intended preparation and use.

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The ELIGARD® pre-connected syringe system device appears to be quite viscous and more difficult to inject compared to the classic ELIGARD®.

Can I use a different needle size for administration?

- **No,** the needle provided in the ELIGARD® package must be used as it is specifically designed for the correct preparation and administration of the medication.[2]
- Substituting it with a different needle size may affect the injection process and compromise proper delivery of the medication.
- Always follow the instructions provided with the product to ensure safe and effective administration.

What happens if I tighten the safety needle too much?

- **Do not overtighten**, as the needle hub may become damaged which could result in leakage of the product during injection.[2]
- Should the needle hub appear to be damaged, or leak, the product **should NOT be used**.[2]
- The damaged safety needle and cap should NOT be replaced and the product should NOT be injected.[2]
- In the event of damage to the needle hub, use a new ELIGARD® carton.[2]

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Why did you make this change?

Was there a problem with the old version?

- As part of Mundipharma's commitment to advancing science and patient care, Mundipharma has introduced the ELIGARD® pre-connected syringe system device.
- This evolution of ELIGARD® is to simplify the mixing and injection process by providing the product in a single, pre-connected syringe system.

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ELIGARD® PRODUCT INFORMATION

ELIGARD®
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ELIGARD® PBS Information: Restricted Benefit
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate.
ELIGARD 6-month 45 mg modified release injection for Central Precocious Puberty (CPP).
Refer to PBS schedule for full information www.pbs.gov.au

Before prescribing, please refer to Product Information.
The Product Information for ELIGARD® can be accessed via the:

TGA website
CLICK HERE

OR

QR code
SCAN HERE:

Adverse events should be reported. Reporting forms and information can be found at https://aems.tga.gov.au/.
Adverse events can also be reported to Mundipharma at drugsafety@mundipharma.com.au.

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at https://www.tga.gov.au/reporting-problems.

References: 1. ELIGARD® Approved Product Information, October 2024; **2.** ELIGARD® Instructions for Use, October 2024. **3.** Data on File, Mundipharma, November 2024.

MUNDELI01586. AU-ELI-2500020. Date of preparation: May 2025.

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MUNDELI01586. AU-ELI-2500020. Date of preparation: May 2025.