

triptorelin. Decapeptyl 6-month is available in boxes of: 1 vial, 1 ampoule and 1 blister containing 1 injection syringe and 2 injection needles.

Manufacturer

Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, Chemin Departemental N° 402, 83870 Signes, France.

The product is procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA0465/261/002

Decapeptyl is a registered trademark of IPSEN PHARMA

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The following information is intended for medical or healthcare professionals only:

INSTRUCTIONS FOR RECONSTITUTION

1. PREPARATION OF THE PATIENT BEFORE RECONSTITUTION

Prepare the patient by disinfecting the injection site. This operation needs to be performed first because once reconstituted, the drug should be injected immediately.

2. PREPARATION OF THE INJECTION

Two needles are provided in the box:

- **Needle 1:** a 20G needle (38 mm of length) without safety device to be used for reconstitution
- **Needle 2:** a 20G needle (38 mm of length) with safety device to be used for injection



The presence of bubbles on top of the lyophilisate is a normal appearance of the product.

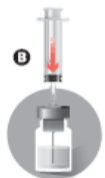
2a

- Take out the ampoule containing the solvent. Tap any solution within the tip of the ampoule back to the main body of the ampoule.
- Screw **Needle 1** (without safety device) on to the syringe. Do not remove the needle protection yet.
- Break open the ampoule with dot face up.
- Remove the needle protection from Needle 1. Insert the needle in the ampoule and draw up all the solvent into the syringe.
- Put aside the syringe containing the solvent.



2b

- Take out the vial containing the powder. Tap any powder which has accumulated at the top of the vial back to the bottom of the vial.
- Remove the plastic tab on top of the vial.
- Take back the syringe containing the solvent and insert the needle through the rubber stopper vertically into the vial. Inject the solvent slowly, so that, if possible, it washes down the entire upper part of the vial.



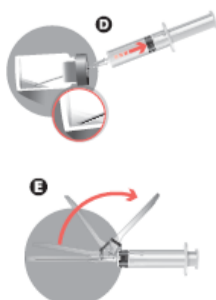
2c

- Pull up Needle 1 above the liquid level. Do not remove the needle from the vial. Reconstitute the suspension, by swirling gently from side to side. Do not invert the vial.
- Continue swirling long enough to obtain a homogenous and milky suspension.
- **Important: Check there is no unsuspended powder in the vial (if any powder clumps are present, continue swirling until they disappear).**



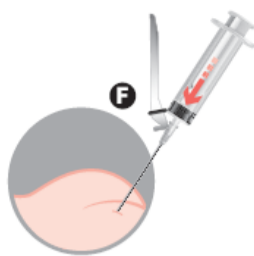
2d

- When the suspension is homogenous, pull down the needle and without inverting the vial, draw up all of the suspension. A small amount will remain in the vial and should be discarded. An overfill is included to allow for this loss.
- Grasp the coloured hub to disconnect the needle. Remove Needle 1 used for the reconstitution from the syringe. Screw on to the syringe **Needle 2**.
- Move the safety sheath away from the needle and towards the syringe barrel. The safety sheath remains in the position you set.
- Remove the needle protection from the needle.
- Prime the needle to remove air from the syringe and inject immediately.



3. INTRAMUSCULAR INJECTION

- To avoid precipitation, inject immediately into the gluteal muscle previously disinfected.

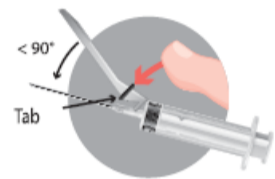


4. AFTER USE

- Activation of the safety system using a one-handed technique.
- Note: Keep your finger behind the tab at all times.

There are two alternatives to activate the safety system:

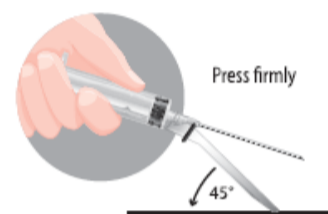
- Method A: push the tab forward with your finger



Method A

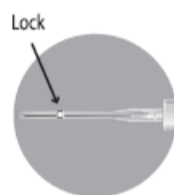
or

Method B: push the sheath to a flat surface



Method B

- In both cases press down with a firm quick motion until a distinct audible click is heard.
- Visually confirm that the needle is fully engaged under the lock.



- Used needles, any unused suspension or other waste materials should be disposed of in accordance with local requirements.