

Instructions for use leaflet

Fulphila®, Prefilled syringe

6 mg / 0.6 ml

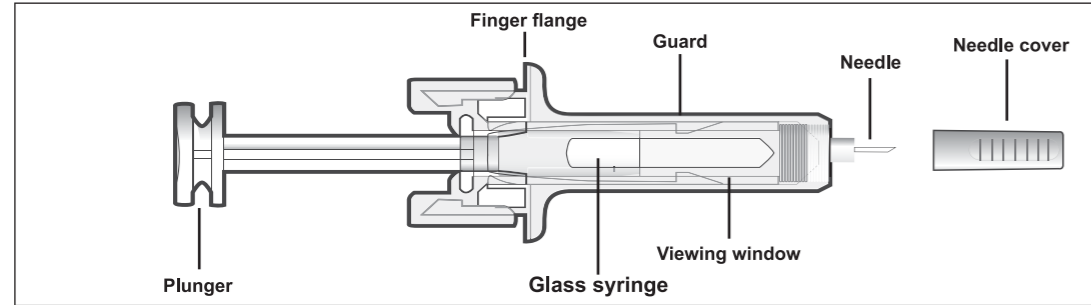
For subcutaneous administration

- Read this entire leaflet carefully before using the medicine.
- Also read the Fulphila patient information leaflet, which is included in the package.

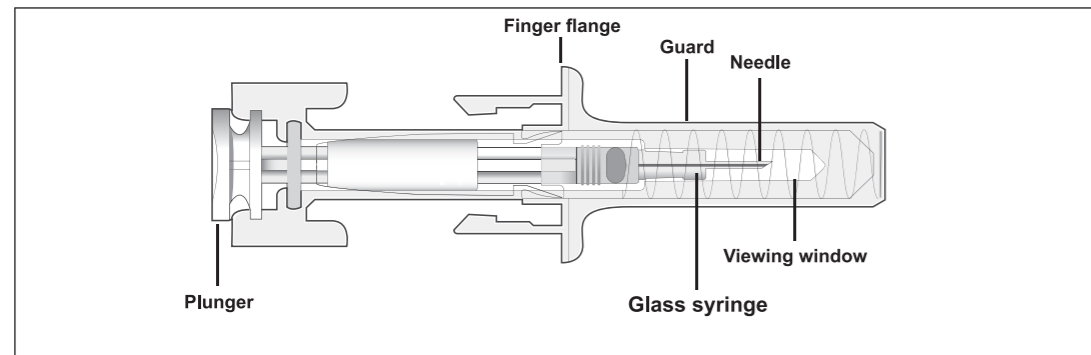
Instructions for use

Guide to parts

Before use:



After use:



Important

Before using Fulphila pre-filled syringe with automatic needle guard, read the following important information:

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or another healthcare provider.
- Fulphila is given as an injection into the tissue just under the skin (subcutaneous injection).
- Do not remove the gray needle cap from the pre-filled syringe until you are ready to inject.
- Do not use the pre-filled syringe if it fell on a hard surface. Use a new pre-filled syringe and call the doctor or another healthcare provider.
- Do not attempt to activate the pre-filled syringe prior to injection.
- Do not attempt to remove the clear syringe safety guard from the pre-filled syringe.
- Do not attempt to remove the peelable label from the pre-filled syringe barrel before administering your injection.

Contact your doctor or another healthcare provider if you have additional questions.

Step 1: Prepare

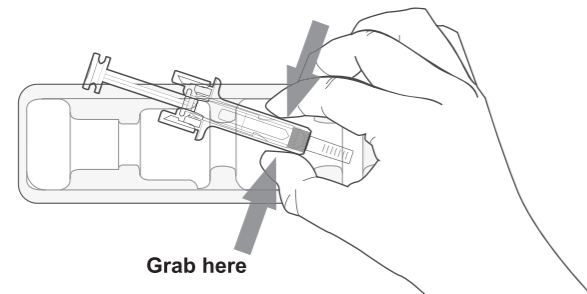
A. Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipe, a cotton ball or gauze pad, a plaster, and a sharps disposal container (not included).

For a more comfortable injection, leave the pre-filled syringe for about 30 minutes to reach room temperature before injection. Wash your hands thoroughly with soap and water.

Place the new pre-filled syringe and other supplies on a clean and well-lit work surface.

- Do not try to warm the syringe by using a heat source such as hot water or a microwave.
- Do not leave the pre-filled syringe exposed to direct sunlight.
- Do not shake the pre-filled syringe.
- Keep the pre-filled syringes out of the reach and sight of children.

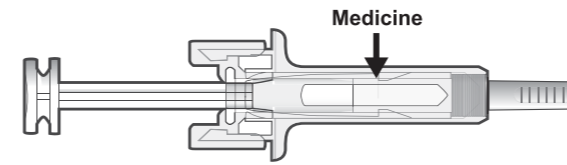
B. Open the tray, by peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.



For safety reasons:

- Do not grasp the plunger.
- Do not grasp the gray needle cap.

C. Inspect the medicine and pre-filled syringe.

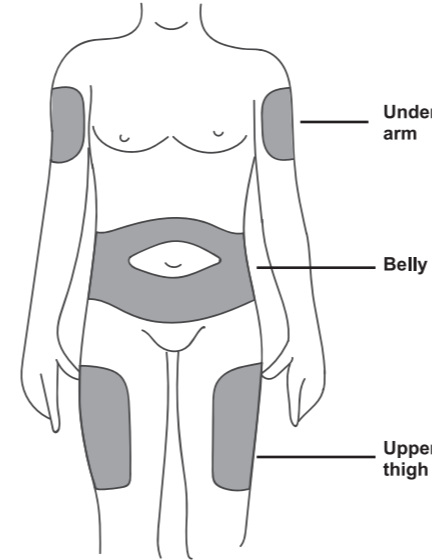


Do not use pre-filled syringe if:

- The medicine is cloudy or there are particles in it. The liquid must be clear and colorless.
- Any part appears cracked or broken.
- The gray needle cap is missing or not securely attached.
- The expiry date that appears on the label has passed the last day of the month shown. In all cases, refer to your doctor or another healthcare provider.

Step 2: Get ready

A. Wash your hands thoroughly. Prepare and clean your injection site.



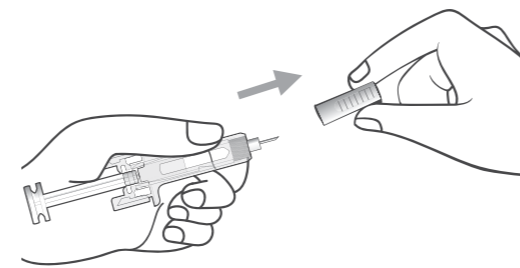
You can inject:

- Upper part of your thigh.
- Belly, except for a 5 cm area around the belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

Clean the injection site with an alcohol wipe. Let your skin dry.

- Do not touch the injection site before injecting.
- Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

B. Carefully pull the gray needle cap straight out and away from your body



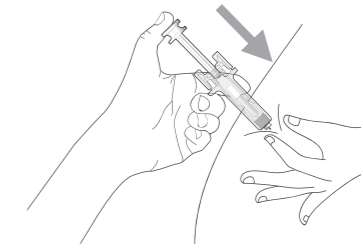
C. Pinch your injection site to create a firm surface.



It is important to keep the skin pinched when injecting.

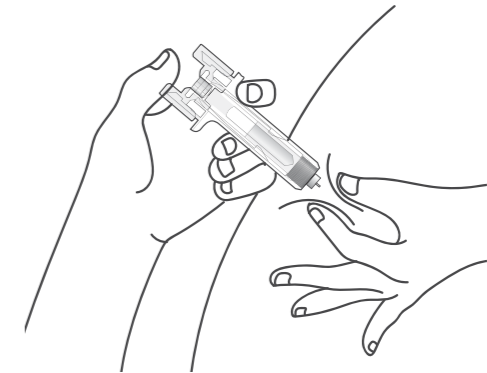
Step 3: Inject

A. Hold the pinch. Insert the needle into the skin.



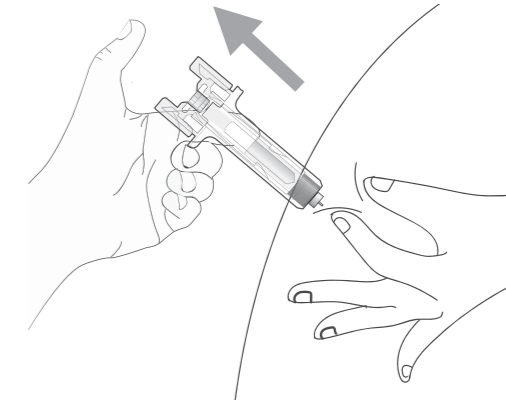
Do not touch the cleaned injection site of the skin.

B. Push the plunger with slow and constant pressure until you feel or hear a snap sound. Push the plunger all the way down even after the sound.



It is important to push the plunger all the way down after hearing the snap sound in order to deliver the full dose.

C. Release your thumb. Then lift the syringe off the skin.



After releasing the plunger, the syringe safety guard will safely cover the syringe needle.

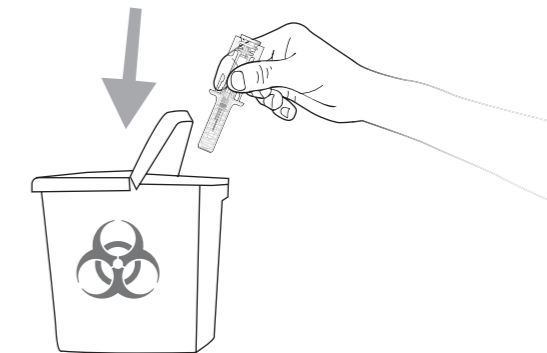
- Do not put the gray needle cap back on the used syringes.

Medical personnel only

The trade name of the preparation should be clearly recorded in the patient file.

Stage 4: Finish

A. Discard the used syringe and additional supplies in a sharps disposal container.



Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines that no longer required. These measures will help protect the environment.

Keep the syringes and sharps disposal container out of sight and reach of children.

- Do not reuse the syringe.
- Do not recycle syringes and do not throw them into household waste.

B. Examine the injection site.

If you see blood, press a cotton ball or a gauze pad on your injection site. Do not rub the injection site. Apply a plaster if needed.

Manufacturer: Mylan Pharmaceuticals Private Limited, Maharashtra, India

Drug registration number at the national drug registry of the Ministry of Health: 164-12-35791-00

Revised in August 2020.

Fulphila, pre-filled syringe 6 mg/0.6 ml PIL PB0820-07

Registration holder: **Dexcel® Ltd.**
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