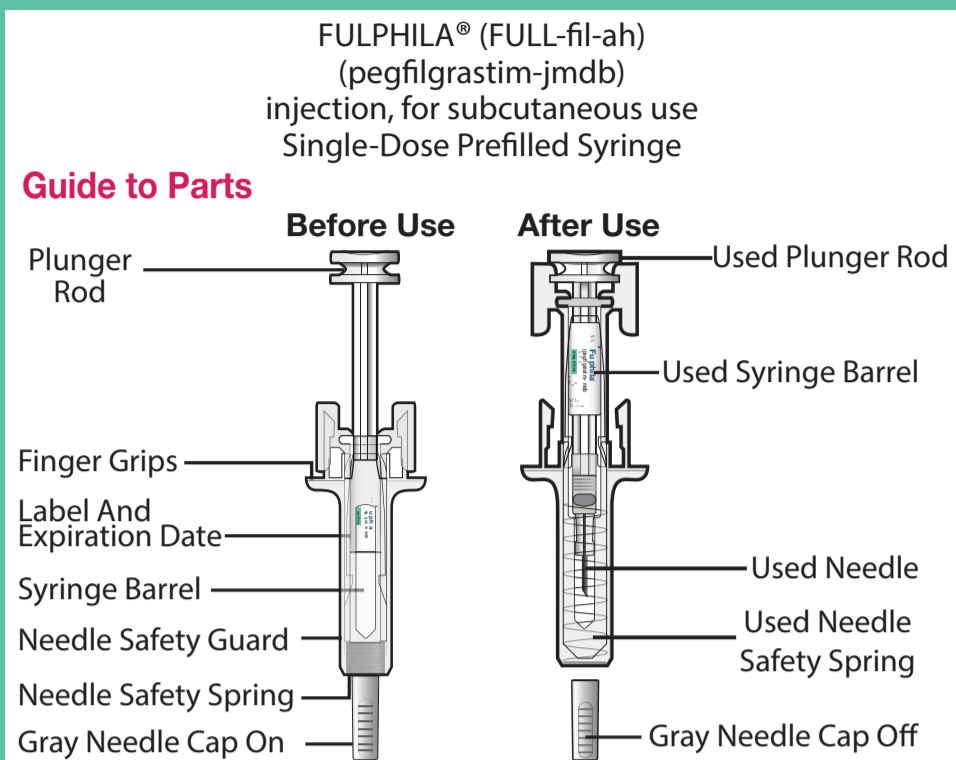


FRONT

600 mm

Instructions for Use



**Important:** The needle is covered by the gray needle cap before use.

**Important Information**  
Read the Patient Information for important information you need to know about Fulphila before using these Instructions for Use.

**Storing the Fulphila prefilled syringe**

- Store Fulphila in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Take Fulphila out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Avoid freezing. If Fulphila is accidentally frozen, allow the prefilled syringe to thaw in the refrigerator before injecting.
- **Do not** use a Fulphila prefilled syringe that has been frozen more than 1 time. Use a new Fulphila prefilled syringe.
- Throw away (dispose of) any Fulphila that has been left at room temperature, 68°F to 77°F (20°C to 25°C) for more than 72 hours or frozen more than 1 time. **See Step 4: Disposing of used prefilled syringes.**
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- For questions about storage, contact your healthcare provider or pharmacist.
- Keep the Fulphila prefilled syringe out of the reach of children.

**Before you use a Fulphila prefilled syringe, read this important information:**

- **It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.**
- The prefilled syringe has a needle safety guard that will be activated to cover the needle after the injection is given. The needle safety guard will help prevent needlestick injuries to anyone who handles the prefilled syringe after the injection has been given.
- Make sure that the name Fulphila appears on the carton and prefilled syringe label.
- Fulphila is given as an injection into the tissue just under the skin (subcutaneous injection).
- **You should not inject a dose of Fulphila to children weighing less than 45 kg from a Fulphila prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the Fulphila prefilled syringe.**
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** use the prefilled syringe if the carton is open or damaged.
- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if it has been dropped on a hard surface. The syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** attempt to activate the prefilled syringe prior to injection.
- **Do not** attempt to remove the needle safety guard from the prefilled syringe.
- **Do not** attempt to remove the label from the prefilled syringe barrel before injecting your dose of Fulphila.

Call your healthcare provider if you have any questions.

Step 1: Gather supplies

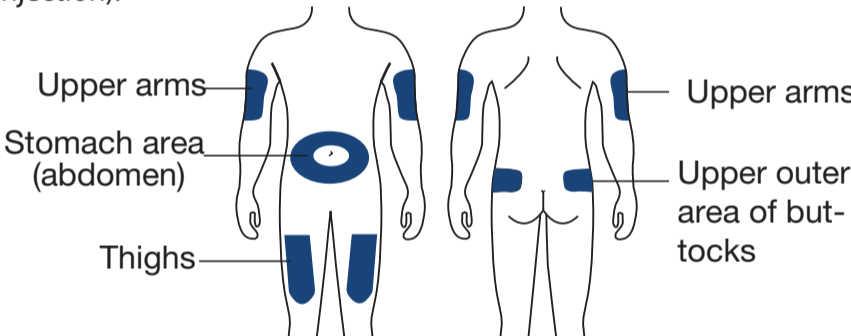
- A** - Find a clean, well-lit and flat work surface, such as a table.
- B** - Take the prefilled syringe carton out of the refrigerator and place it on your clean work surface. Allow it to reach room temperature for 30 minutes before giving an injection.
- C** - Remove the prefilled syringe tray from the carton.
- D** - Wash your hands thoroughly with soap and water.
- E** - Gather the supplies for the injection:
  - 1 alcohol wipe
  - 1 cotton ball or gauze pad
  - 1 adhesive bandage
  - an FDA-cleared sharps disposal container

Step 2: Prepare for injection

- F** - Open the tray by peeling away the cover. Grab the needle safety guard to remove the prefilled syringe from the tray.
- For safety reasons:
- **Do not** grab the plunger rod.
  - **Do not** grasp the gray needle cap.

- G** - Inspect the medicine and prefilled syringe. **Make sure the medicine in the prefilled syringe is clear and colorless.**
  - Do not** use the prefilled syringe if:
    - The medicine is cloudy or discolored, or contains flakes or particles.
    - The prefilled syringe has been dropped.
    - Any part appears cracked or broken.
    - The gray needle cap is missing or not securely attached.
    - The expiration date printed on the label has passed.
- In all cases, use a new prefilled syringe and call your healthcare provider.

- H** - Prepare and clean the injection site.
- There are 4 injection sites that you can use:
- thigh
  - stomach area (abdomen), except for a 2-inch area right around the navel (belly button)
  - upper outer area of the buttocks (only if someone else is giving you the injection), and
  - the outer area of the upper arm (only if someone else is giving you the injection).

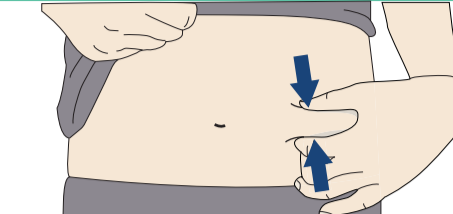


- Clean the injection site with an alcohol wipe. Let the skin dry.
- **Do not** touch this area again before injecting.
  - **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
  - If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

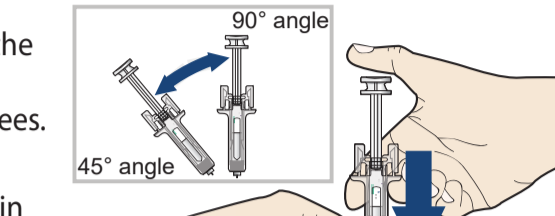
- I** - Hold the prefilled syringe by the needle safety guard. When ready, carefully pull the gray needle cap straight off and away from the body.
- **Do not** twist or bend the gray needle cap.
- **Do not** hold the prefilled syringe by the plunger rod.
- **Do not** put the gray needle cap back onto the prefilled syringe. Dispose of (throw away) the gray needle cap in your household trash.

Step 3: Inject the dose

- J** - Pinch the cleaned injection site to create a firm surface.
- Keep skin pinched while injecting.**



- K** - Hold the pinch. Insert the needle into the skin between 45 to 90 degrees.
- Do not touch the cleaned area of the skin**



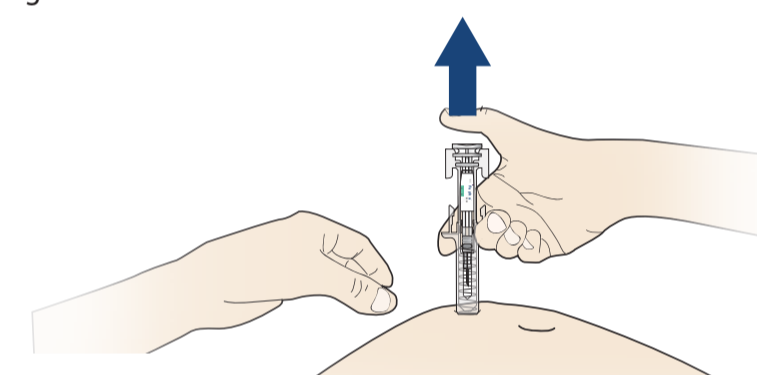
- L** - Using slow and constant pressure, push the plunger rod until it reaches the bottom.



- The plunger must be pushed fully in order to inject the full dose.**

- M** - Once the entire dose has been injected, the needle safety guard will be triggered. You can do either of the following:
  - Release the plunger until the entire needle is covered and then remove the needle from the injection site.

- or**
- Gently remove the needle from the injection site and release the plunger until the entire needle is covered by the needle safety guard.



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

- Once the needle has been removed from the injection site, dispose of the syringe and needle in your sharps disposal container right away. **See "Step 4: Disposing of used prefilled syringes".**

- **If the needle safety guard is not activated or only partially activated, discard the product (without replacing the needle cap). See "Step 4: Disposing of used prefilled syringes".**
- **If your injection is given by another person, they should also be careful when removing the needle from your skin in order to prevent accidental needlestick injury and possible infections.**

- **When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received the full dose. Call your healthcare provider right away.**

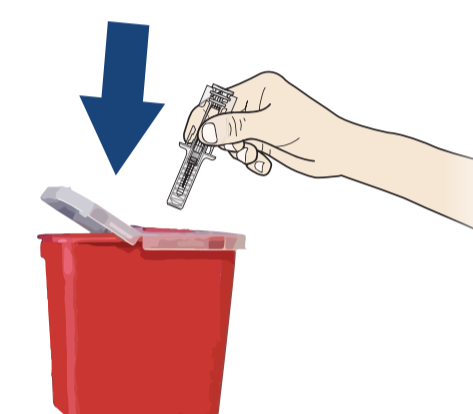
- N** - Examine the injection site. If there is blood, press a cotton ball or gauze pad on the injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

Step 4: Disposing of used prefilled syringes

- Put the used prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away the syringe in the household trash.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic
  - can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out
  - upright and stable during use
  - leak-resistant
  - properly labeled to warn of hazardous waste inside the container

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at <http://www.fda.gov/safesharpsdisposal>.



**Important:** Keep the sharps disposal container out of the reach of children.

- **Do not** reuse the prefilled syringe.
- **Do not** recycle prefilled syringes or throw them into household waste.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.



Manufactured by:  
**Biocon Biologics Inc.**  
245 Main St, 2nd Floor  
Cambridge, MA 02142, U.S.A.  
U.S. License No. 2324

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Revised: 08/2023

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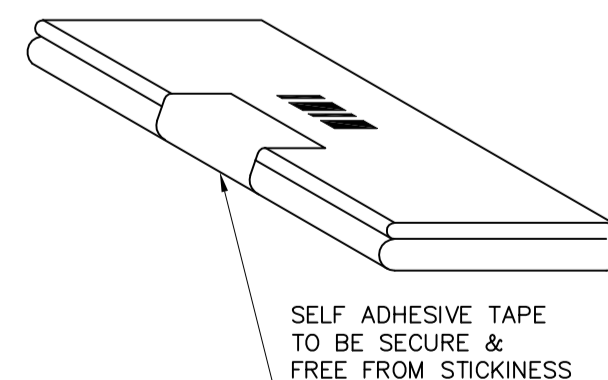
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Open Size : 390(W) x 600(H) mm ; Folded Size : 100(W) x 40(H) mm ; PAPER : 60gsm Maplitho Paper  
BOOKLET TO BE SEALED WITH SELF ADHESIVE TAPE  
SAP CODE : 650006091

Pharmacode Size: 10x10mm



REFERENCE BLISTER LAYOUT NO.

1) PGB065191143 M1 (EUROPE PACK)

DRAWING No.  
**BOOKLET-1**

PGB065191143 M1 (EUROPE PACK)

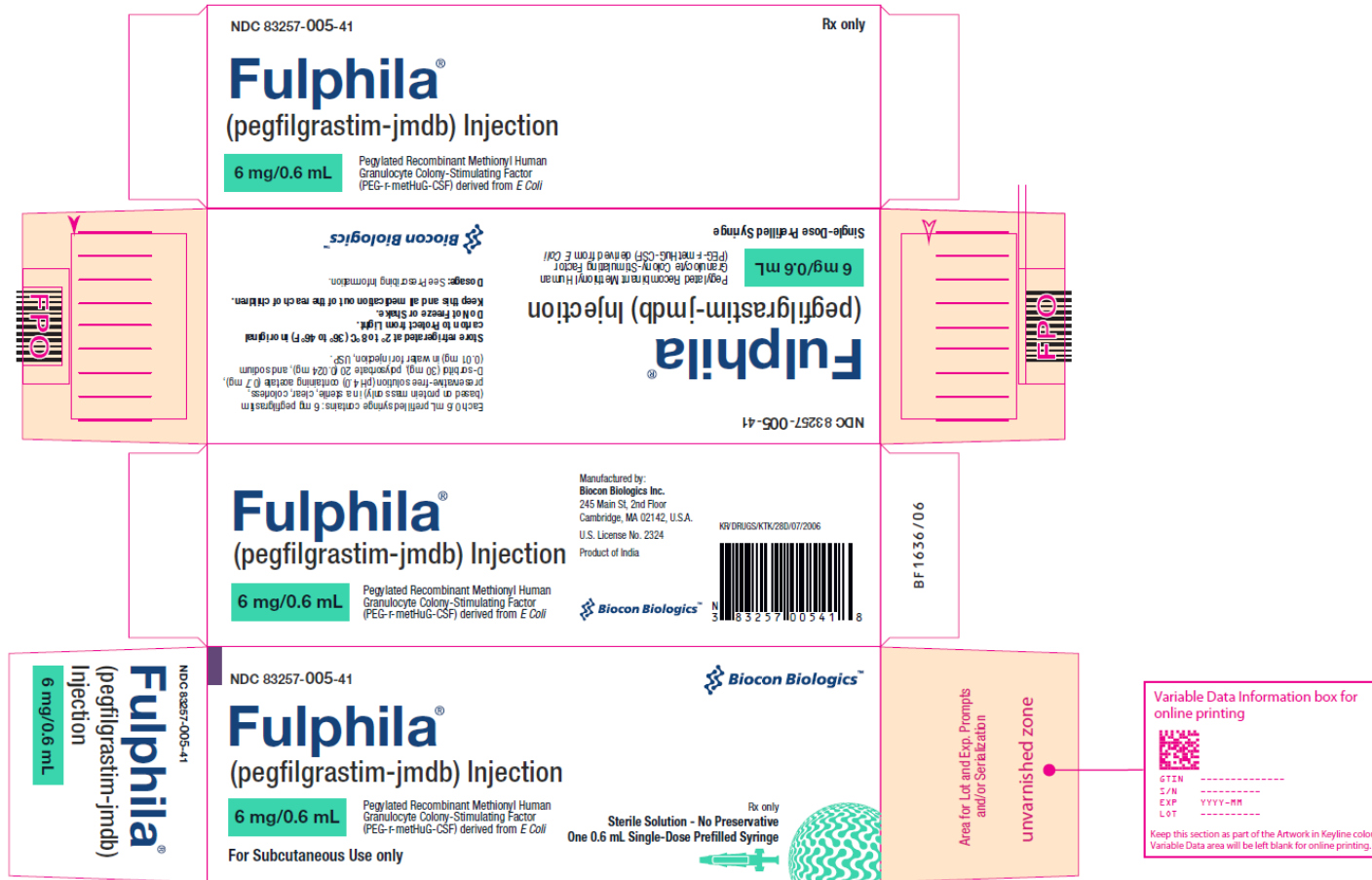
Biocon Biologics		Proof Date: 31.08.2023		DRAFT-3	
Description	Fulphila <sup>®</sup> (pegfilgrastim-jmdb) 6 mg - One 0.6 mL Single-dose Prefilled Syringe	No. of Colors	4	Page Count	1
Item Code(s)	GTIN TBD	Spot Print Colors			
Component Type	IFU	Site Code	(b) (4)	Process Print Colors	(b) (4)
Barcode Info	TBD	Lotus Code	N/A	Non-Print Colors	
TrackWise PR No.		Keyline/Drawing	See Below*		
Dimensions	390 mm x 600 mm	Fold Size	100 mm x 40mm	Minimum Font	Myriad Reg & Bold 10/10 point
Proof and Images	Please check thoroughly to ensure it meets your requirements as NO liability will be accepted for consequential loss. Barcodes provided on this proof are for purposes of encodation only and are not to be used for grading according to ANSI Standards. Print Vendor is responsible for ensuring barcode scanability in final printed product.				

1.14.1.1 DRAFT-LABELLING-CARTON-AND-CONTAINER-LABELS-CLEAN-PDF

Reponse to Information Request Dated 17<sup>TH</sup> AUG 2023 (BLA 761075/S-025)

**FULPHILA™ (Pegfilgrastim-jmdb) Injection**  
 6 mg/0.6 mL

**Carton label**



1.14.1.1 DRAFT-LABELLING-CARTON-AND-CONTAINER-LABELS-CLEAN-PDF

Reponse to Information Request Dated 17<sup>TH</sup> AUG 2023 (BLA 761075/S-025)

FULPHILA™ (Pegfilgrastim-jmdb) Injection  
6 mg/0.6 mL

**Syringe label**

The diagram shows a syringe label with a yellow and black striped area on the left. The label contains the following text and elements:

- Top: NO TEXT AREA
- Left side: XXXXX, FPO, B F 1635 / 06
- Top right: NO TEXT AREA
- Center: NDC 83257-005-41, Rx only
- Product name: **Fulphila**<sup>®</sup> (pegfilgrastim-jmdb) Injection
- Dosage: **6 mg/0.6 mL** Single-Dose Prefilled Syringe
- Usage: **For Subcutaneous Use Only**
- Manufacturer: Mfd. by: **Biocon Biologics Inc.**, U.S. License No. 2324, Product of India
- Barcode: N 3 8 3 2 5 7 1 0 0 5 4 1 8
- Bottom: NO TEXT AREA
- Bottom left: NO VARNISH AREA, Batch Coding Area 18 x 13mm
- Bottom right: XXXXXXXXXXXX, YYYYY-MM

1.14.1.1 DRAFT-LABELLING-CARTON-AND-CONTAINER-LABELS-CLEAN-PDF

Reponse to Information Request Dated 17<sup>TH</sup> AUG 2023 (BLA 761075/S-025)

FULPHILA™ (Pegfilgrastim-jmdb) Injection  
6 mg/0.6 mL

Tray label

NDC 83257-005-41 Rx only


**Fulphila**<sup>®</sup>  
(pegfilgrastim-jmdb)  
Injection

**6 mg/0.6 mL**

**For Subcutaneous Use Only**  
Pegylated Recombinant Methionyl Human  
Granulocyte Colony-Stimulating Factor  
PEG-r-metHuG-CSF) derived from *E Coli*

Lot XXXXXXXXXX  
Exp YYYY-MM


One 0.6 mL  
Single-Dose  
Prefilled Syringe



**Biocon Biologics**<sup>™</sup>  
Manufactured by:  
**Biocon Biologics Inc.**  
245 Main St, 2nd Floor  
Cambridge, MA 02142, U.S.A.  
U.S. License No. 2324  
Product of India  
KR/DRUGS/KTK/28D/07/2006

Each 0.6 mL prefilled syringe contains: 6 mg pegfilgrastim (based on protein mass only) in a sterile, clear, colorless, preservative-free solution (pH 4.0) containing acetate (0.7 mg), D-sorbitol (30 mg), polysorbate 20 (0.024 mg), and sodium (0.01 mg) in water for injection, USP.

**Dosage:** See Prescribing Information.  
**Keep this and all medication out of the reach of children.**  
**Store refrigerated at 2° to 8°C (36° to 46°F) in original carton to Protect from Light.**  
**Do Not Freeze or Shake.**  
**Sterile Solution - No Preservative**



832570054118

BFT1637/06

PEEL  
HERE

This label may not be the latest approved by FDA.  
For current labeling information, please visit <https://www.fda.gov/drugsatfda>



Susan  
Kirshner

Digitally signed by Susan Kirshner

Date: 10/13/2023 08:25:01AM

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