

Instructions for Use
UDENYCA™ (yoo-den-i-kah)
(pegfilgrastim-cbqv)
Injection
Single-Dose Prefilled Syringe

Guide to Parts

Before use

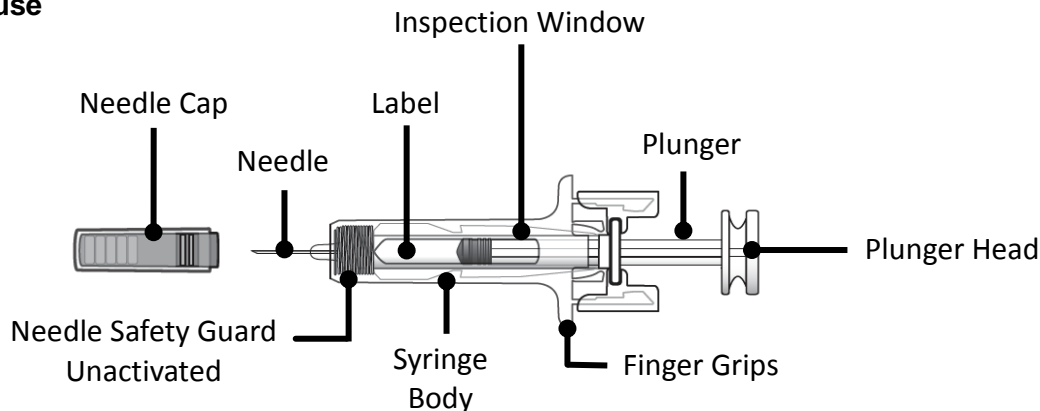


Figure 1

Important: The needle is covered by a needle cap before use

After use

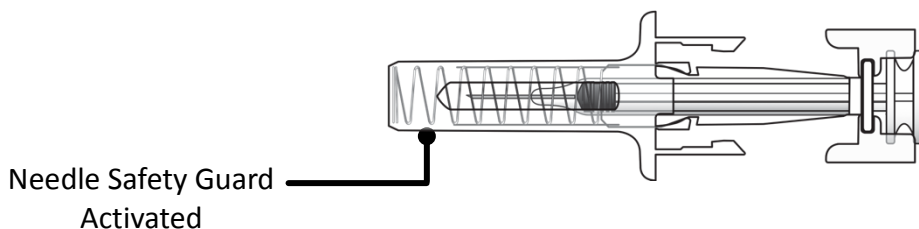


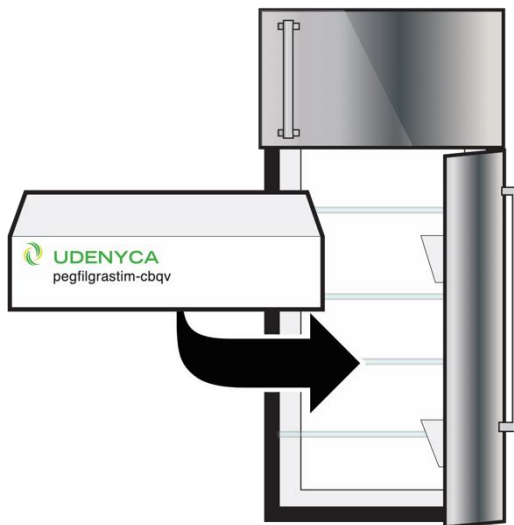
Figure 2

Important

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

Storing the UDENYCA prefilled syringe

- Store UDENYCA prefilled syringes in the refrigerator between 36°F to 46° F (2°C to 8°C).
- Keep the UDENYCA prefilled syringe in the original carton to protect from light.
- **Do not** freeze UDENYCA.
 - If UDENYCA is accidentally frozen, allow the prefilled syringe to thaw in the refrigerator before injecting.
 - Throw away (dispose of) any UDENYCA prefilled syringes that have been frozen more than 1 time.
- Throw away (dispose of) any UDENYCA prefilled syringes that have been left out at room temperature for more than 48 hours.
- Keep the UDENYCA prefilled syringe out of the reach of children.



Using the prefilled syringe

- **It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.**
- Make sure that the name UDENYCA appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 6 mg/0.6 mL.
- You should not inject a dose of UDENYCA to children weighing less than 45 kg from a UDENYCA prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the UDENYCA prefilled syringe.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe
- **Do not** remove the needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if the carton is open or damaged.
- **Do not** use a prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** attempt to activate the needle safety guard prior to injection

Call your healthcare provider if you have any questions.

Prepare the injection

1 - Remove carton from refrigerator and check expiration date

1A: Remove the carton from the refrigerator and check the expiration date printed on the carton. (See Figure 3)

Do not use if the expiration date has passed.

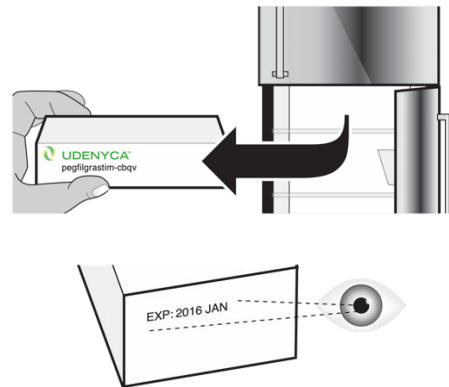


Figure 3

1B: Open the carton and remove the sealed syringe tray. (See Figure 4)

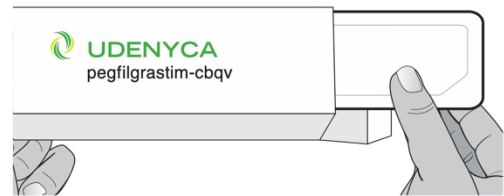


Figure 4

2 - Allow UDENYCA to reach room temperature and gather supplies

2A: Place the sealed syringe tray on a flat, clean work surface and allow it to sit at room temperature for at least 30 minutes. (See Figure 5)

Do not attempt to warm up the syringe in any other way, such as a microwave, hot water, or direct sunlight.

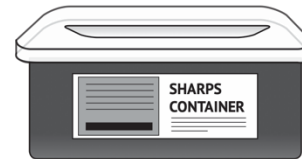


Figure 5

2B: Gather the following supplies: (See Figure 6)

- alcohol wipe
- cotton ball or gauze
- 1 adhesive bandage
- sharps disposal container

Sharps Disposal Container



Alcohol Wipe



Cotton Ball



Adhesive Bandage



Figure 6

3 - Wash your hands and remove syringe from tray

3A: Wash your hands well with soap and warm water. (See Figure 7)



Figure 7

3B: Open the tray by peeling away the cover. Remove the prefilled syringe from the tray by grasping the middle of the syringe body and carefully pulling it out of the tray. (See Figure 8)

For Safety reasons:

- **Do not** grab the plunger, plunger head.
- **Do not** grab the needle cap.

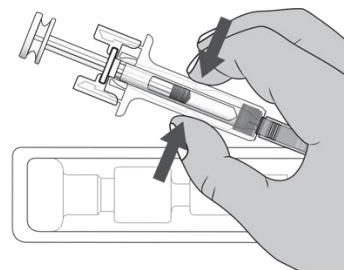


Figure 8

4 - Inspect the syringe and medicine

Check the medicine through the Inspection Window. The medicine should be clear and colorless. It is normal to see 1 or more air bubbles in the syringe. Removal of the air is not needed. (See Figure 9)

Do not use the prefilled syringe if:

- the medicine appears discolored or cloudy.
- the medicine contains lumps, flakes, or particles.
- it appears used or damaged.
- if the 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.

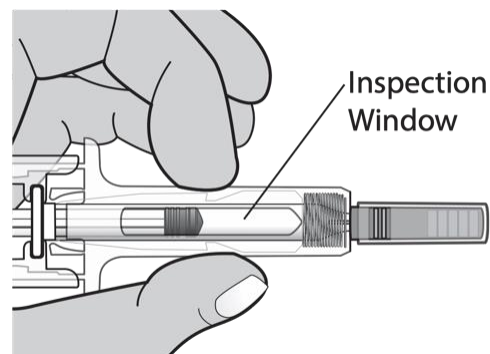


Figure 9

Select and clean injection site

5 - Select and clean the injection site

5A: Select the injection site. The recommended injection sites for a subcutaneous injection are the: (See Figure 10)

- Abdomen (except for a two-inch area surrounding the navel)
- Thighs
- Back of upper arms (only if someone else is giving you the injection)
- Upper outer area of the buttocks (only if someone else is giving you the injection)

Do not inject into moles, scars, birthmarks, or areas where the skin is tender, bruised, red, or hard.

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.

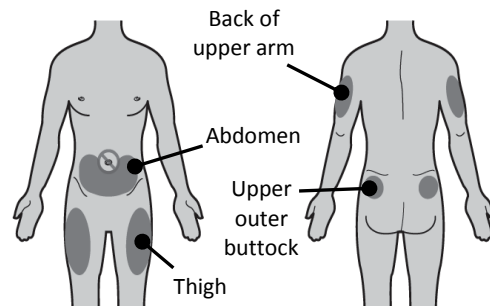


Figure 10

5B: Clean the injection site with an alcohol wipe. (See Figure 11)

Do not touch this area again before injection.

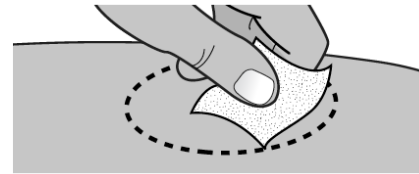


Figure 11

Inject the dose

6 - Remove needle cap

Remove the needle cap by pulling it straight off. (See Figure 12)

- **Do not** remove the needle cap from the prefilled syringe until you are ready to inject.
- **Do not** twist or bend the needle cap.
- **Do not** hold the prefilled syringe by the plunger rod
- **Do not** put the needle cap back onto the syringe. Dispose of (throw away) the needle cap in your household trash
- **Do not** use the prefilled syringe if it has been dropped with the needle cap removed.

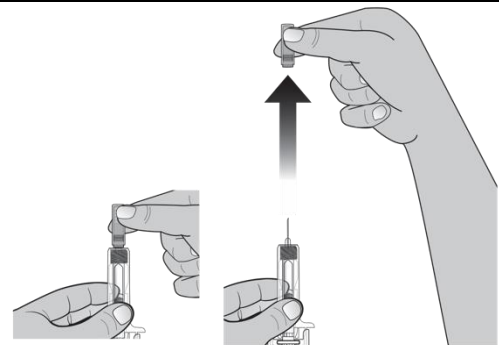


Figure 12

7 - Position fingers

Grasp the body of the syringe like a dart (just under the finger grips) with your thumb and index fingers. (See Figure 13)

- **Do not** touch the plunger or grasp the syringe above the finger grips.

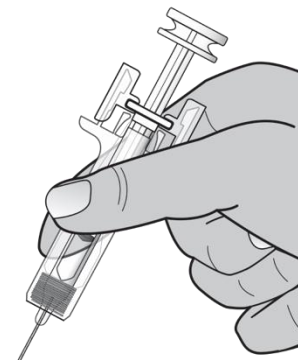


Figure 13

8 – Pinch the skin and insert the needle

8A: Use your free hand to gently pinch the cleaned injection site to create a firm surface. (See Figure 14)

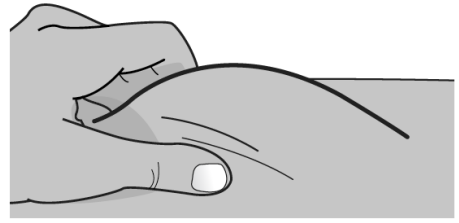


Figure 14

8B: Hold the pinch. Insert the needle into the skin at a 45 to 90-degree angle. (See Figure 15)

- **Do not** touch the plunger head while inserting the needle into the skin.
- **Do not** touch the cleaned area of the skin

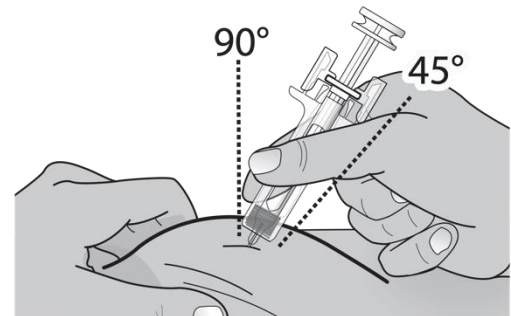


Figure 15

8C: After fully inserting the needle, release the pinched skin and use your free hand to stabilize the bottom of the syringe.

Then move your other hand into injection position with your thumb on the plunger head. (See Figure 16)

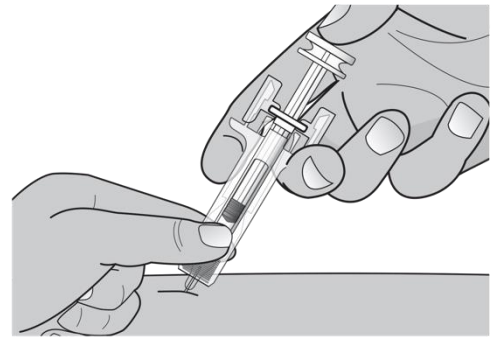


Figure 16

9 – Push plunger head down to deliver dose

9A: Using slow and constant pressure, push the plunger head down until it reaches the bottom. This will help to ensure that you receive the full dose. (See Figure 17)

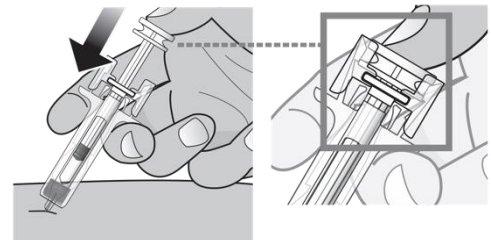


Figure 17

9B: While the needle is still inserted, slowly move your thumb back, allowing the plunger to rise. This will release the needle safety guard to safely cover the needle. Then remove the syringe from the injection site. (See Figure 18)

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

- If you see drops of blood at the injection site, treat by pressing a cotton ball or gauze to the site as needed.

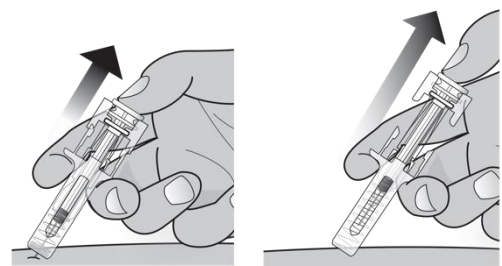


Figure 18

Dispose

10 – Dispose of used prefilled syringes

Put the used prefilled syringe into an FDA-cleared sharps disposal container right away after use. **Do not** throw away the syringe in the household trash. (See Figure 19)

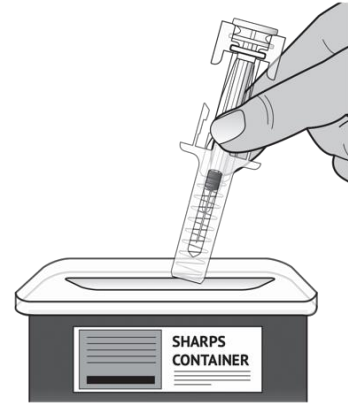


Figure 19

- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a 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>.
- **Do not** reuse the prefilled syringe.
- **Do not** recycle prefilled syringes or sharps disposal container or throw them into household trash.

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

Issued: 11/2018



UDENYCA™ (pegfilgrastim-cbqv)

Manufactured by: Coherus BioSciences, Inc., Redwood City, California 94065-1442

U.S. License No. 2023

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For more information go to www.UDENYCA.com, or call 1-800-4UDENYCA (1-800-483-3692)

PMD-0005, Rev. 01