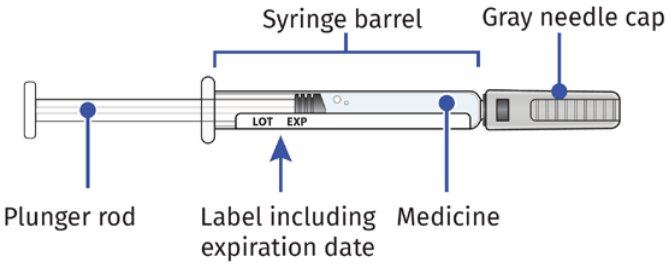
Healthcare Provider INSTRUCTIONS FOR USE

UDENYCA [yoo-den-i-kah] **ONBODY™**

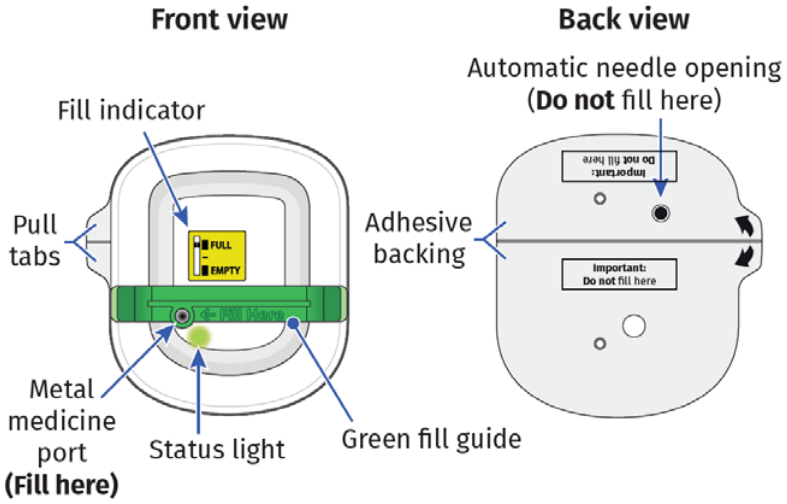
(pegfilgrastim-cbqv)
injection, for subcutaneous use

Guide to Parts

UDENYCA Prefilled Syringe



On-body Injector for UDENYCA



Important

READ THE FOLLOWING INSTRUCTIONS BEFORE USING UDENYCA ONBODY

Prescribing Information

- See Prescribing Information for information on UDENYCA.
- The on-body injector is for adult patients only.
- The on-body injector is not recommended for patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome.
- For patients who have had severe skin reactions to acrylic adhesives, consider the benefit-risk profile before administering pegfilgrastim via the on-body injector for UDENYCA.

Application Information

- The on-body injector should be applied to intact, non-irritated skin on the abdomen or back of the arm. The back of the arm may only be used if there is a caregiver available to monitor the status of the on-body injector.
- The on-body injector has a self-adhesive backing to attach it to the skin, **do not** use additional materials to hold it in place as this could lead to a missed or incomplete dose of UDENYCA.

Environmental Information

- **Do not** expose the on-body injector for UDENYCA to the following environments as the on-body injector may be damaged and the patient could be injured:
    - Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
    - Radiation treatment
    - Oxygen rich environments such as hyperbaric chambers.

Cautions

- **Do not** use UDENYCA ONBODY to deliver any other drug product.
- **Do not** use the on-body injector if its packaging has been previously opened, or the expiration date on the carton or any components has passed.
- **Do not** use if the name UDENYCA does not appear on UDENYCA ONBODY carton.
- **Do not** modify the on-body injector.
- **Do not** fill the UDENYCA on-body injector on the adhesive side. Use the metal medicine port.
- **Do not** attempt to reapply the on-body injector.
- **Do not** use if either the on-body injector or prefilled syringe is dropped. Start again with a new on-body injector or prefilled syringe.

Storage Information

- Store the ONBODY in the refrigerator at 36°F to 46°F (2°C to 8°C) until ready for use. If the ONBODY is stored at room temperature for more than 12 hours, **do not** use. Start again with a new ONBODY.
- Keep the prefilled syringe in the carton until use to protect from light.
- **Do not** freeze the ONBODY.
- **Do not** separate the components of UDENYCA ONBODY until ready for use.

For all questions, call Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692). If a patient calls you regarding any on-body injector problems, call Coherus BioSciences at 1 800-4UDENYCA (1-800-483-3692).

Step 1: Prepare

A| Remove ONBODY from the refrigerator and open carton.

Place the syringe tray and on-body injector tray on a clean, flat, well-lit work surface. Allow to come to room temperature for 30 minutes prior to use. **Do not** warm the UDENYCA ONBODY components using a heat source.

Check to make sure it contains:

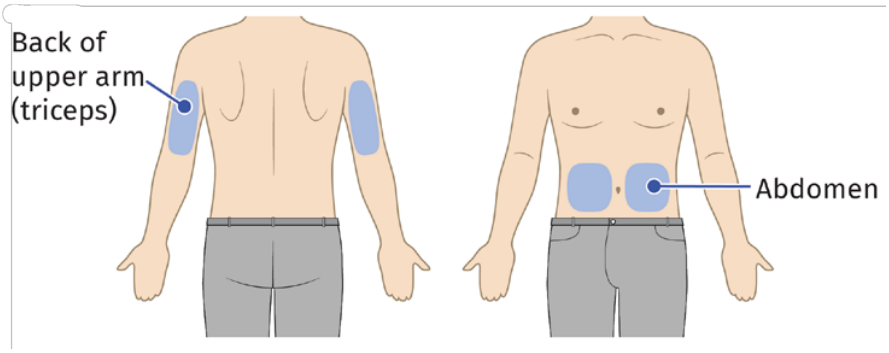
- One UDENYCA prefilled syringe
- One on-body injector for UDENYCA
- UDENYCA Patient Information
- UDENYCA Prescribing Information
- Instructions for Use for healthcare provider
- Instructions for Use for patient

Check the above listed items for damage and check the expiry date on the syringe tray and on-body injector tray.

Do not use the on-body injector:

- if its packaging has been previously opened
- if the packaging or trays appear to be damaged or have been dropped
- if the expiry date on the syringe tray or on-body injector tray has passed.

B| Choose the patient's injection site.



Choose the flattest site for the on-body injector application.

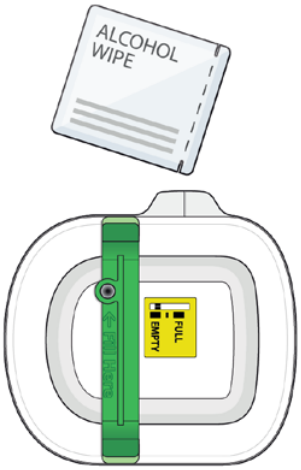
Ask the patient about their ability to monitor and remove the on-body injector.

- You can use the left or right side of the abdomen, except for a two-inch area right around navel.
- You can use the back of upper arm only if there is a caregiver available to monitor the status of the on-body injector.
- Apply the on-body injector to intact, non-irritated skin.
- **Do not** apply the on-body injector on areas with scar tissue, moles, or excessive hair. In case of excessive hair, carefully trim hair to get the on-body injector close to the skin.

- **Do not** apply the on-body injector on areas where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the on-body injector.
- **Do not** apply the on-body injector on surgical sites.
- **Do not** apply the on-body injector on areas where the on-body injector will be affected by folds in the skin.

C| Clean an area on the injection site larger than the on-body injector adhesive backing.

- Thoroughly clean the site with alcohol to enhance on-body injector's adherence to the skin. Only use alcohol to clean the skin.
- Make sure the skin is oil-free prior to applying the on-body injector.
- Allow the skin to completely dry on its own (e.g. without blowing on or fanning the area) before attaching the on-body injector.
- **Do not** touch this area again before attaching the on-body injector.



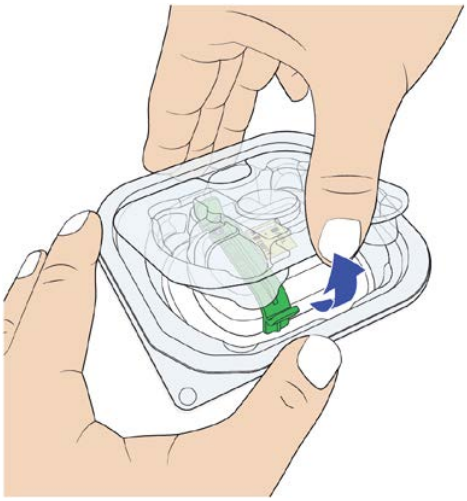
Step 2: Get ready

A| Open on-body injector tray and remove plastic lid.

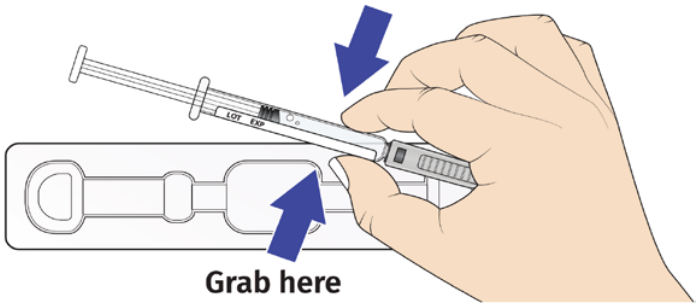
Wash your hands before use.

Open the on-body injector tray by fully removing the tray cover and removing the plastic lid.

- **Do not** remove the on-body injector from the tray before filling it.
- **Do not** remove the green fill guide.



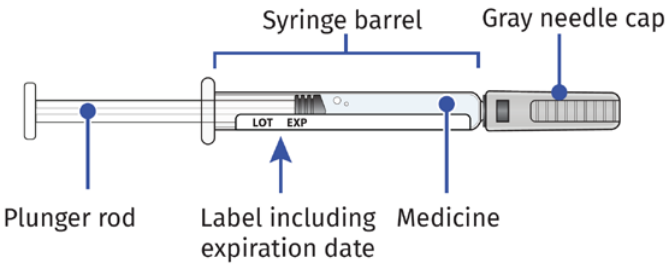
B| Remove UDENYCA prefilled syringe from tray.



For safety reasons:

- **Do not** grasp the gray needle cap.
- **Do not** remove the gray needle cap until ready to fill the on-body injector.
- **Do not** grasp the plunger rod.

C| Inspect medicine and UDENYCA prefilled syringe. UDENYCA liquid should always be clear and colorless.



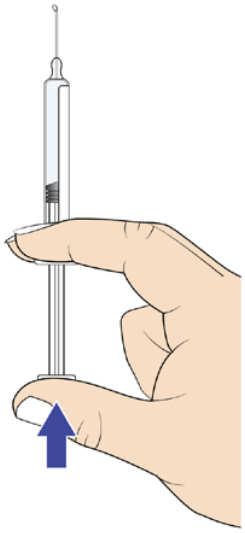
- **Do not** use if the liquid contains particulate matter or discoloration is observed prior to administration.
- **Do not** use if any part appears to be damaged, cracked or broken.
- **Do not** use if the gray needle cap is missing or not securely attached.
- **Do not** use if the expiration date printed on the label has passed.
- **Do not** remove the gray needle cap until ready to fill the on-body injector.
- **Do not** shake the prefilled syringe.

In all the above cases, start again with a new UDENYCA ONBODY. Call Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).

D| Remove air bubbles in prefilled syringe.

Injecting air bubbles into the on-body injector could interfere with the full-dose delivery.

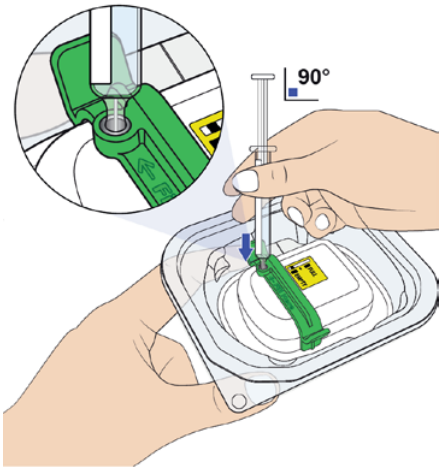
- Remove the gray needle cap.
- Gently tap the syringe with your finger until air bubbles rise to the top.
- Slowly push air out of the syringe, taking care to not expel medicine.
- A small droplet at the tip of the needle during air purging is normal.
- **Do not** recap the syringe.



E| Orient the syringe with the needle facing downwards. Center the needle directly over the metal medicine port at a 90-degree angle. Insert the needle all the way into the port, avoiding sides.

Insert needle into metal medicine port at a 90-degree angle only.

- **Do not** fill the UDENYCA on-body injector on the adhesive side. Use the metal medicine port.
- **Do not** touch the plunger until the needle is fully inserted into the metal medicine port.
- **Do not** move the needle in the metal medicine port.
- **Do not** insert the needle more than once.
- **Do not** bend the needle. Avoid spilling the medicine.
- **Do not** remove the green fill guide before filling the on-body injector.



F| Fully depress the plunger rod to expel entire contents of the prefilled syringe into the on-body injector.

After filling completely, you will hear two beeps. The status light will start to flash green.

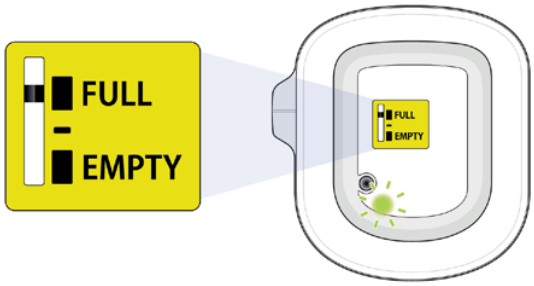
Remove the needle straight from the metal medicine port and dispose the empty syringe right away into a puncture proof container.

- **Do not** recap the needle.

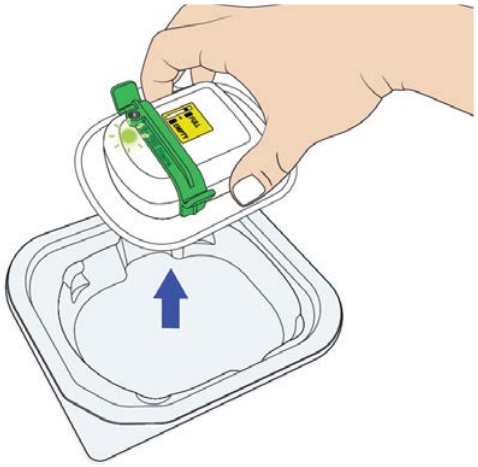
G| Check to see if the on-body injector is full.

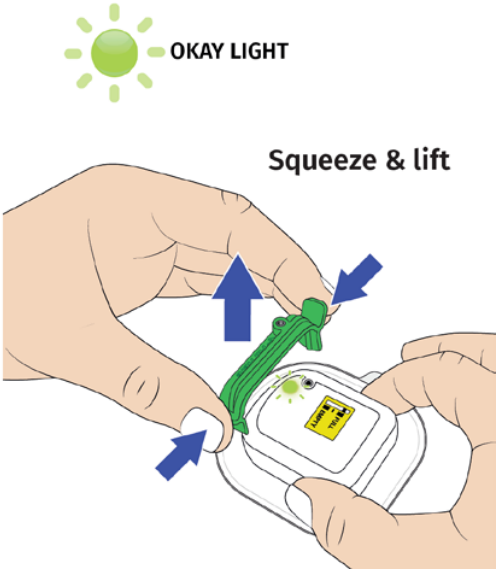
You should see the green status light flashing and a black line next to FULL on the fill indicator. If this is not the case, **do not** use.

Start again with a new UDENYCA ONBODY, and call Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).



H| Remove on-body injector from tray, then firmly squeeze and lift the green fill guide away from the on-body injector.





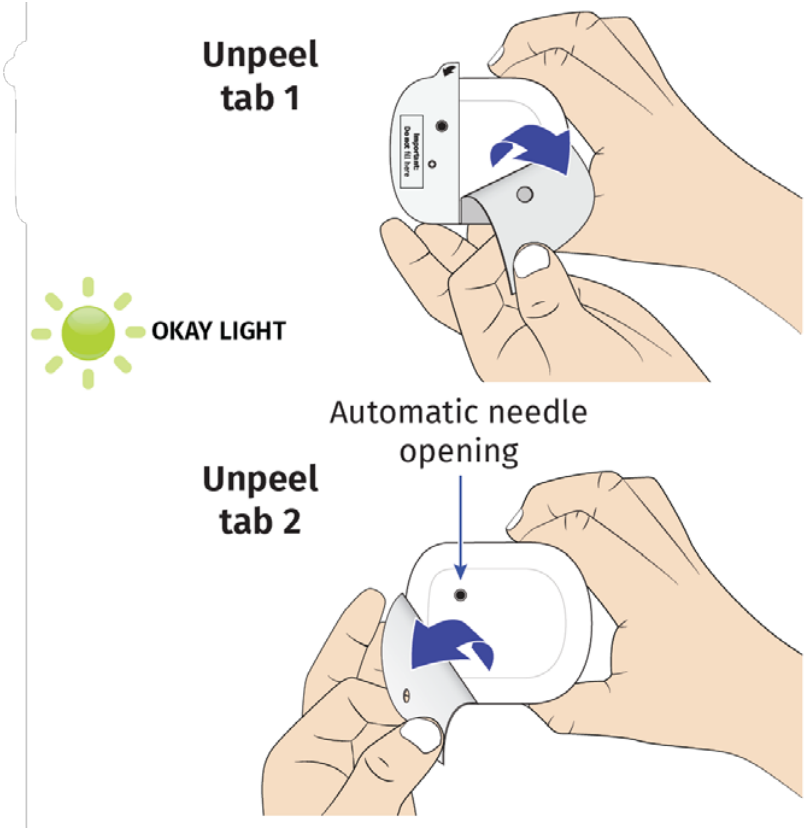
Dispose of green fill guide.

A drop of medicine may be visible on the metal medicine port when the green fill guide is removed.

Step 3: Apply

A| Peel away both pull tabs to show the adhesive. Never touch hands or gloves to the adhesive.

Make sure skin is dry prior to applying the on-body injector.



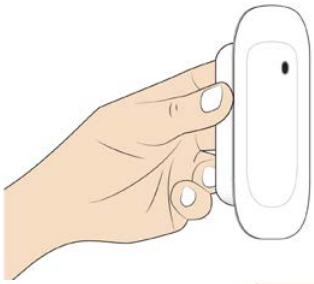
- **Do not** touch or contaminate the automatic needle opening.
- **Do not** pull off the adhesive pad or fold it.
- **Do not place adhesive on skin that is damp.**

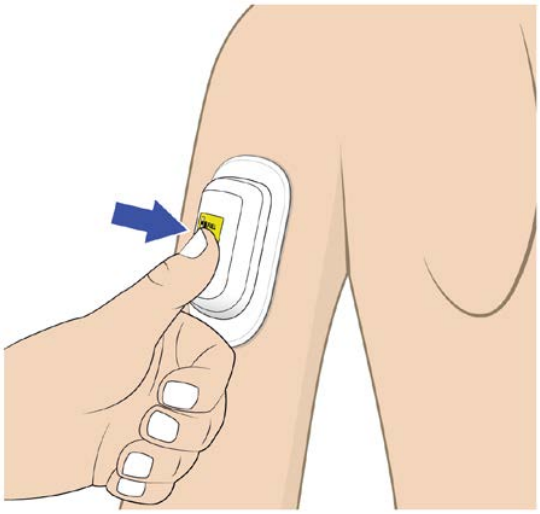
In all cases, start again with a new UDENYCA ONBODY.

Call Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).

B| Securely apply the on-body injector without folding and without wrinkling to the cleaned injection site so it is visible and can be monitored by the patient or caregiver.

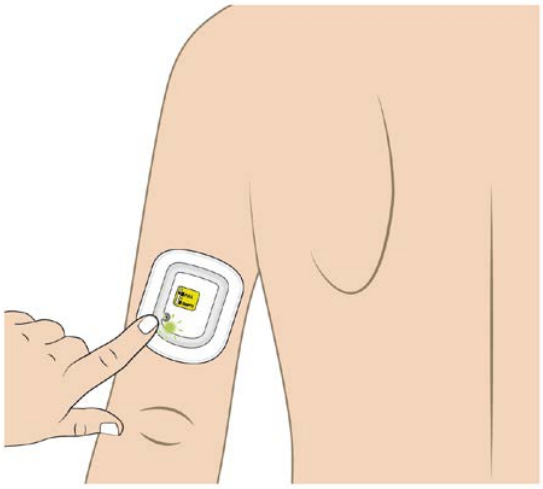
- **Do not** touch the adhesive.
- Grasp the on-body injector's plastic case with your fingertips and only by sides, keeping fingers off of the adhesive.
- **Do not** let the adhesive bend or curl while applying the on-body injector to skin.
- **Important:** Once on the skin, **press firmly on the on-body injector** to ensure proper adhesion to the patient's skin.
- Press around the entire adhesive so it lies down without folds or wrinkles.
- Hold the top of the on-body injector and run finger around the adhesive to create a secure attachment.
- **Do not** use other materials to secure the on-body injector to the patient that could cover audio/visual indicators or compress the on-body injector against the patient's skin.





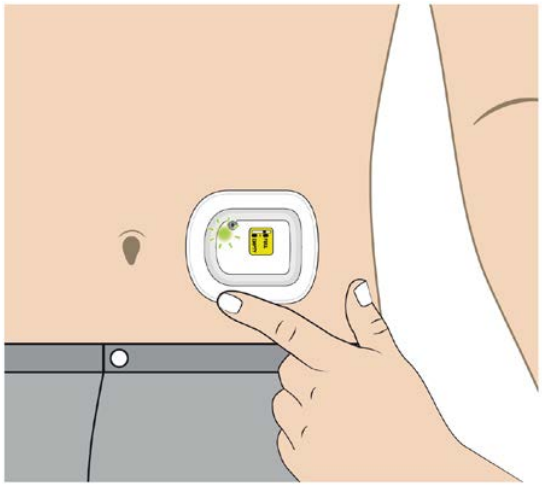
Back of upper arm (triceps)

Vertical with the light facing down toward the elbow



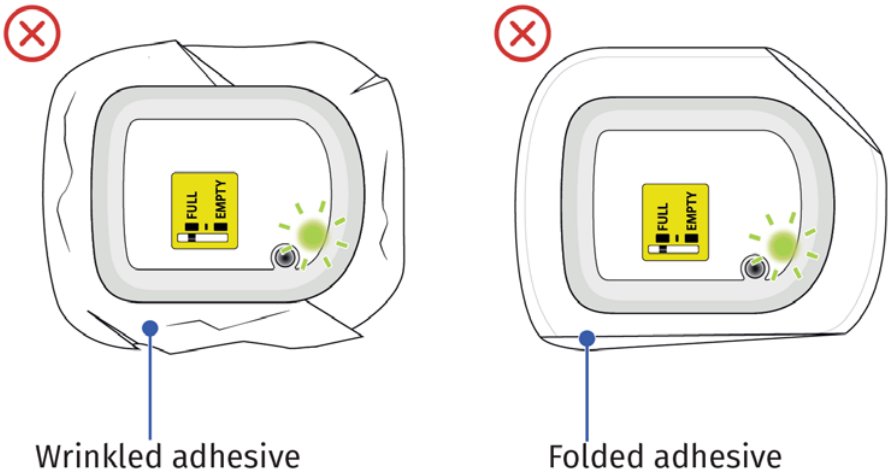
Abdomen

Horizontal with the light facing up and visible to the patient



Check the quality of adhesion before sending the patient home.

If the adhesive is wrinkled or has folds anywhere that prevent the on-body injector from securely adhering, remove the on-body injector. Start again with a new ONBODY and call Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).



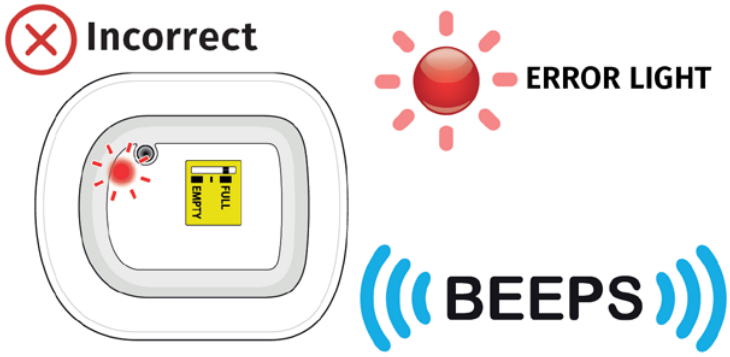
Step 4: Finish

A| Provide the Patient Instructions for Use Booklet for the patient to take home. Fill in the Dose Delivery information on the Patient Instructions for Use Booklet, and review the following instructions with your patient:

- The on-body injector will always flash a slow green light to let them know it is working properly.
- The patient should keep the on-body injector dry for at least 3 hours after it was placed on their skin.
- After approximately 27 hours the on-body injector will start to deliver the dose.
- Immediately before dose delivery starts the injection needle will be automatically inserted into the skin.
- When the dose delivery starts it will take about 5 minutes to complete. During this time, the on-body injector will flash a fast green light.
- **When dose delivery is complete, the on-body injector will sound a long beep, and the status light will turn SOLID GREEN. The needle will retract automatically.**
- **Do not remove the on-body injector until the status light is SOLID GREEN.**
- If the red error light is flashing, or the adhesive is noticeably wet (saturated), or the on-body injector is dislodged, the patient should contact their healthcare provider immediately as they may need a replacement dose.
- The patient should remain in a place where they can monitor the on-body injector for the entire dose delivery. The patient should avoid activities and settings that may interfere with wearing and monitoring during the dosing of UDENYCA administered by the on-body injector or could cause the OBI to fall off. For example, avoid traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector (this includes the approximately 5-minute delivery period plus an hour post-delivery).
- If the patient has an allergic reaction during the delivery of UDENYCA, the patient should remove the on-body injector and call his or her healthcare provider or seek emergency care right away.
- If placed on the back of the arm, remind the patient that a caregiver must be available to monitor the on-body injector.
- The on-body injector has a self-adhesive backing to attach it to the skin.
- **Do not** use other materials to hold it in place as this could cover audio/visual indicators or compress the on-body injector against the patient's skin, as this could lead to a missed or incomplete dose of UDENYCA.
- Always dispose of the empty on-body injector in a sharps disposal container as instructed by your healthcare provider or by state or local laws.
- Keep the on-body injector at least four inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances. Failure to keep the on-body injector at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of UDENYCA.

Attention!

What to do if you hear beeping or when you look at status light and it is flashing red?



If at any time the on-body injector beeps continuously for five minutes, and the status light is flashing red, take the on-body injector off of the patient.

- **Do not** apply the on-body injector to the patient if red error light is on.
- **Do not** leave the on-body injector on the patient if red error light is on.

In all cases, **do not** use. Start over with a new UDENYCA ONBODY, and call 1-800-4UDENYCA (1-800-483-3692).

If the patient reports the red status light is on, they may not have received the full dose. Schedule a follow-up appointment and report the incident to Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).

What to do if the adhesive becomes saturated with fluid or the on-body injector is dripping.

If the patient reports an on-body injector leak, they may not have received the full dose. Schedule a follow-up appointment and report the incident to Coherus BioSciences at 1-800-4UDENYCA (1-800-483-3692).

Manufactured by:
Coherus BioSciences, Inc.
Redwood City, CA 94065-1442
US License No. 2023

https://udenyca.com
1-800-4UDENYCA (1-800-483-3692)
Issued: 12/2023
PMD-0214 Rev. 00

Electromagnetic Compatibility

The delivery system is designed to conform to the electromagnetic compatibility (EMC) standard IEC 60601-1-2:2020 and to operate accurately in conjunction with other medical equipment which also meets the requirements of this standard under home and hospital use environments.

To avoid electromagnetic interference (EMI) that may affect the performance of the delivery system [(i) Dose accuracy, (ii) treatment duration, (iii) Injection Depth, (iv) Visual and audible feedback], do not use the delivery system near sources of strong electric and magnetic interference (EMI), such as MRI, ionizing radiation, CT, diathermy, electromagnetic security systems (e.g., metal detectors), and large electric motors. In addition, portable and mobile RF communication equipment, such as RF emitters, cellular telephones, 2-way radios, Bluetooth™ devices, and microwave ovens in close proximity to this device may affect the operation of the delivery system. Some of these EMI sources (mostly RF emitters) may not be visible and the device can potentially be exposed to fields from these EMI sources without the user's awareness.

If you identify or suspect that external RF sources or other equipment are influencing delivery system operation (from known or unknown sources), try to (as applicable) increase the delivery system distance from the EMI source.

Electromagnetic Emissions

The delivery system has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

The delivery system has been tested for Electromagnetic Emissions		
Emissions Test	**Test Level**	**Compliance Level**
Radiated Emission per IEC 60601-1-2/ CISPR 11	Frequency range: 30 - 1000 MHz	Group 1 Class B, Home Healthcare Environment
Radiated Emission per ETSI EN 301 489-1, ETSI EN 301 489-17 and EN 55032	Frequency range: 30 - 6000 MHz	Class B, Home Healthcare Environment

If this delivery system does cause harmful interference to radio or television reception, which can be determined by turning the radio or television off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the radio or television to an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician.

Electromagnetic Immunity

The delivery system has been tested to comply in either a Home Healthcare Environment or Professional Healthcare Environment.

The delivery system has been tested for Electromagnetic Immunity		
Immunity Test	**IEC Test Level**	**Compliance Level**
Electrostatic discharge (ESD) per IEC 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	±8 kV Contact ±15 kV Air
Radiated RF EM fields per IEC 61000-4-3	10 V/m, 80 MHz- 2.7 GHz, 80 % AM at 1 kHz	10 V/m, 80 MHz-2.7 GHz, 80 % AM at 1 kHz
Rated Power Frequency (50/60 Hz) magnetic fields per IEC 61000-4-8	30 A/m	30 A/m
Proximity magnetic fields per IEC 61000-4-39	8 A/m, 30kHz, CW; 65 A/m, 134.2kHz, PM 2.1kHz 50%; 7.5 A/m, 13.56MHz, PM 50kHz 50%	8 A/m, 30kHz, CW; 65 A/m, 134.2kHz, PM 2.1kHz 50%; 7.5 A/m, 13.56MHz, PM 50kHz 50%

Proximity fields from RF wireless communications equipment Immunity

The delivery system is tested per IEC 61000-4-3 at Frequencies and Levels as specified below to ensure Enclosure Port Immunity to RF wireless communications equipment.

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710, 745, 780	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
810, 870, 930	800 to 960	GSM 800/900, TETRA 800,	Pulse modulation 18 Hz	28
1720, 1845, 1970	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240, 5500, 5785	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
If necessary to achieve the immunity test level, the distance between the transmitting antenna and the me equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Delivery System. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this delivery system adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Symbols Glossary

Description	Symbol/Sub clause
Name or trade mark of the product	UDENYCA®
Part number	REF
Name or trade name and address of the manufacturer	
Serial number or batch code, preceded by the word 'LOT', or the serial number/NDC number;	LOT SN
Warnings and/or precautions to take (in text format)	N/A
Storage temperature and any other special storage and/or handling conditions (for the combination)	
Humidity limitation (for the combination)	
Pressure limitation (for the combination)	
Do not use if package is damaged	
Keep away from sunlight	
Keep dry	
For electrical devices - Water and dust ingress rating	IP68
For electrical devices – refer to instruction for use	
"Rx only" labeling of prescription devices	℞ Only

Description	Symbol/Sub clause
Sterile & Sterilization by EO	
Expiration date (Use by)	
The device is for single use	
Should not enter the MRI scanner room	
Type BF applied parts	
CSA Certificate	
Battery specification Li-MnO2 Battery 3V/850mAH (CR14250)	N/A
WEEE directive compliance	
UDENYCA® (pegfilgrastim-cbqv) prefilled syringe	
On-body injector for UDENYCA® (pegfilgrastim-cbqv)