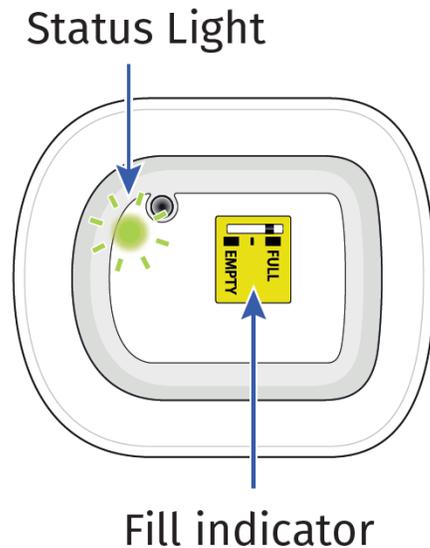




## Get to Know Your On-body Injector

### Parts and Signals



### Status Light



#### Flashing Green:

The on-body injector is working properly. **Do not** remove the on-body injector if the status light is flashing green.



#### Solid Green (or off):

Signals dose delivery is complete. Check to see if fill indicator reads empty.



#### Flashing Red:

On-body injector error. If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away as you may need a replacement dose.



#### Fill indicator:

Black line shows how much UDENYCA is in the on-body injector.

## Important Information

### On-body Injector for UDENYCA Description

- The on-body injector for UDENYCA is intended for delivery of UDENYCA. This on-body injector delivers UDENYCA with an injection under-the-skin (subcutaneous). See the Patient Information that comes with your on-body injector for important information.
- Your healthcare provider will use a prefilled syringe with UDENYCA to fill the on-body injector prior to applying it. The prefilled syringe with UDENYCA and the on-body injector are provided to your healthcare provider as part of UDENYCA ONBODY. The on-body injector is applied directly to your skin using a self-adhesive backing. The on-body injector lets you know its status with sounds and lights.

### Warnings

- You should only receive a dose of UDENYCA on the day your healthcare provider tells you.
- You should not receive your dose of UDENYCA any sooner than 24 hours after you finish receiving your chemotherapy. The on-body injector for

UDENYCA is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector on your skin.

- If you have concerns about your medicine, call your healthcare provider right away. Serious allergic reactions can happen with UDENYCA. Ask your caregiver to be nearby for the first use. Plan to be in a place where you or your caregiver can closely monitor the on-body injector for UDENYCA for about 5-minutes during UDENYCA delivery and for an hour after the delivery.
- **Do not** take UDENYCA if you have had a serious allergic reaction to pegfilgrastim products or to filgrastim products.
- Tell your healthcare provider if you have had severe skin reactions to acrylic adhesives.
- If you have an allergic reaction during the delivery of UDENYCA, remove the on-body injector by grabbing the edge of the adhesive pad and peeling off the on-body injector. Get emergency medical help right away. **Caution the needle may be exposed.** Dispose of the on-body injector into a sharps disposal container right away.
- Call your healthcare provider right away if you have severe pain or skin discomfort around your on-body injector.
- Call your healthcare provider right away if you have pain in your left upper stomach area or left shoulder area. This pain could mean your spleen is enlarged or ruptured.
- Call your healthcare provider or get emergency medical help right away if you get any of these symptoms of acute respiratory distress syndrome (ARDS): fever, shortness of breath, trouble breathing, or a fast rate of breathing.
- Call your healthcare provider right away if you experience any of these symptoms of kidney injury (glomerulonephritis): puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.
- Call your healthcare provider if you have persistent or worsening redness or tenderness at the application site (may be a sign of infection).
- The on-body injector is for adult patients only.

### **Wearing the On-body Injector**

- This on-body injector delivers UDENYCA with an under-the-skin (subcutaneous) injection.
- The on-body injector is small, for one-time use, lightweight, battery-powered, and waterproof up to 5 feet (1.5 meters) for 1 hour.
- The on-body injector can be worn in a shower. After showering, check the on-body injector to make sure it has not become loose (dislodged).
- Avoid getting body lotions, creams, oils or cleaning agents near the on-body injector as these products may loosen the adhesive. Before your next scheduled UDENYCA dose, avoid use of lotions, creams, or oils on your arms and stomach area (abdomen).

- Only expose the on-body injector to temperatures between 41°F and 104°F (5°C and 40°C).
- **Do not** use bathtubs, hot tubs, whirlpools, or saunas while wearing the on-body injector. This may affect your medicine.
- **Do not** expose the on-body injector to direct sunlight. If the on-body injector is exposed to direct sunlight for more than 1 hour, it may affect your medicine. Wear the on-body injector under clothing.
- **Do not** sleep on the on-body injector or apply pressure during wear, especially during dose delivery. This may affect on-body injector performance.
- **Do not** peel off or disturb the on-body injector adhesive before your full dose is complete. This may result in a missed or incomplete dose of UDENYCA.

### **Environmental Precautions**

- **Do not** expose the on-body injector to the following because the on-body injector may be damaged and you could be injured:
  - Diagnostic imaging (e.g., CT Scan, MRI, Ultrasound, X-ray)
  - Radiation treatment
  - Oxygen rich environments, such as hyperbaric chambers.
- Keep the on-body injector at least 4 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.
- Avoid activities and places that may interfere with monitoring during the dosing of UDENYCA administered by the on-body injector. For example, **avoid** traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector for UDENYCA (this includes the 5-minute dose delivery period plus an hour post-delivery).
- If you must travel by airplane **before** the approximately 5-minute dose delivery period with the on-body injector, avoid airport X-ray scans. Request a manual pat down instead. Use care during a manual pat down to help prevent the on-body injector from being accidentally removed. For more information go to: **<http://www.tsa.gov/travelerinformation/travelers-disabilities-and-medical-conditions>**

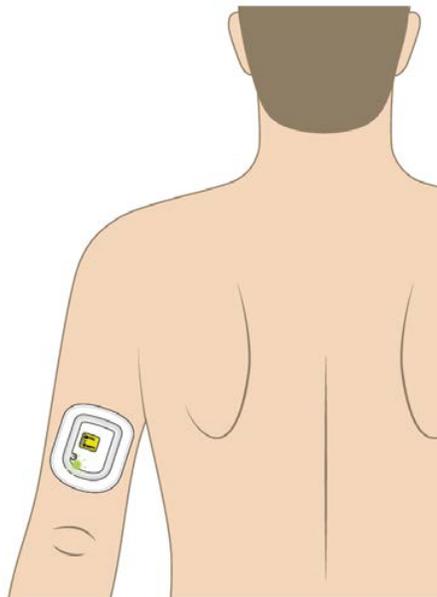
A healthcare provider who is familiar with UDENYCA should answer your questions. For general questions or support call **1-800-4UDENYCA (1-800-483-3692)** or visit **[www.udenyca.com](http://www.udenyca.com)**.

## Step 1: Monitor On-body Injector

A| For the next 27 hours, occasionally check the status light for at least 10 seconds. If the status light is flashing green, it is okay.



- Keep the on-body injector and adhesive backing dry for at least 3 hours after it was placed on your skin, and for 3 hours prior to dose delivery.
- Be careful not to bump the on-body injector, or knock the on-body injector off your body.
- The on-body injector has a self-adhesive backing to attach it to the skin. **Do not** add other materials to hold it in place as this could lead to a missed or incomplete dose of UDENYCA.



- If the on-body injector was placed on the back of your arm, a caregiver must be available to monitor the status of the on-body injector.
- If the on-body injector comes away from your skin at any time, **do not** reapply it. Call your healthcare provider right away as you may need a replacement

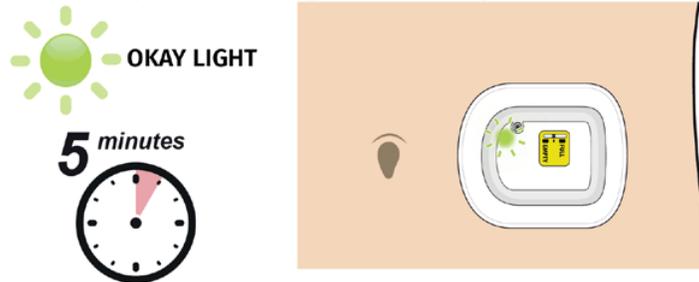
dose. **Caution the needle may be exposed.** Dispose of the on-body injector into a sharps disposal container right away.

- If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away, as you may need a replacement dose.

## Step 2: Observe Dose Delivery

**A| After about 27 hours, your on-body injector will begin to deliver your dose of UDENYCA.**

- Right before the injection starts the injection needle will be automatically inserted into the skin.
- Dose delivery will take around 5-minutes to complete. The on-body injector will flash a fast, green light.
- You may hear the pump working. This is okay.



- When dose delivery is complete, a long beep will sound and the status light will turn solid green.
- If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away, as you may need a replacement dose.
- **Do not remove the on-body injector if the status light is flashing green.**



**Check your on-body injector often for leaks during the 5-minute dose delivery. If the on-body injector was placed on the back of your arm, a caregiver must be available to check your on-body injector.**



Incorrect



Noticeably wet adhesive



Incorrect



Dripping fluid from on-body injector

- If the adhesive is noticeably wet or dripping with medicine, call your healthcare provider right away, as you may need a replacement dose.

### Step 3: Verify Dose Complete

A) After the beep, check the color of the status light.



Correct



 FINISH LIGHT

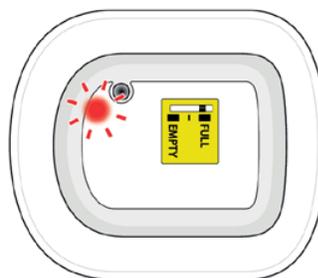
Check to see if the status light is **SOLID GREEN** or has switched off. This means the dose is complete.

If the dose is complete, go to the next step.

**Do not** remove the on-body injector if the status light is flashing green.



Incorrect



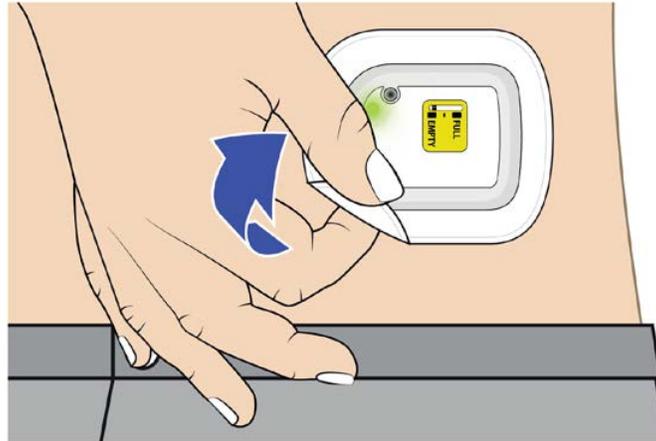
 **ERROR LIGHT**

 **BEEPS**

If you see the status light is **FLASHING RED**, and your on-body injector is beeping, your on-body injector is not functioning properly.

Call your healthcare provider right away, as you may need a replacement dose.

**B| Grab the edge of the adhesive pad. Slowly peel off the on-body injector.**



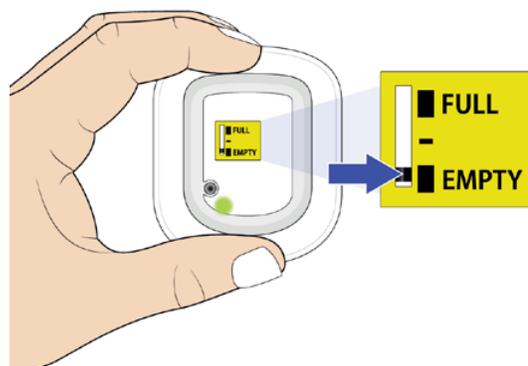
- **Do not** grasp the on-body injector itself to try to pull it off of your body.
- If medicine has leaked or the adhesive is noticeably wet or dripping, call your healthcare provider right away, as you may not have received your full dose and you may need a replacement dose.
- Remove any extra adhesive using soap and water.

#### **Step 4: Finish**



**Check to see if your on-body injector is empty.**

- Check your status light. Watch for at least 10 seconds. If the status light is solid green or it has switched off, it is okay.
- You should see a black line next to the EMPTY indicator. If the on-body injector is not empty, call your healthcare provider right away, as you may need a replacement dose.



- If you hear beeping, or when you check the status light and it is flashing red, call your healthcare provider right away.
- If the needle is exposed, call your healthcare provider right away.

**A| Check off the box below to record how your on-body injector looks after use.**

- Status light is solid green or the status light has switched off. This means that the delivery is complete.
- On-body injector leaked, call your healthcare provider right away, as you may need a replacement dose.
- Status light is red, call your healthcare provider right away, as you may need a replacement dose.

**B| Properly dispose of the on-body injector.**

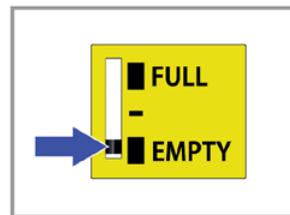
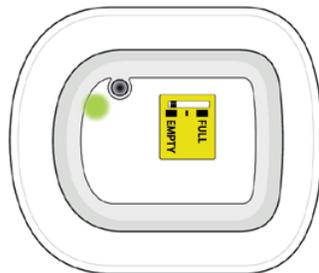
- After on-body injector removal, place the on-body injector in a sharps disposal container whether the needle is exposed or not.
- The on-body injector contains batteries, electronics, and a needle. Put the on-body injector in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) the on-body injector in your household trash.**
- 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, and
  - 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.

- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Keep the used on-body injector and sharps disposal container away from children.**



## Frequently Asked Questions

How do I know it is safe to remove the on-body injector?

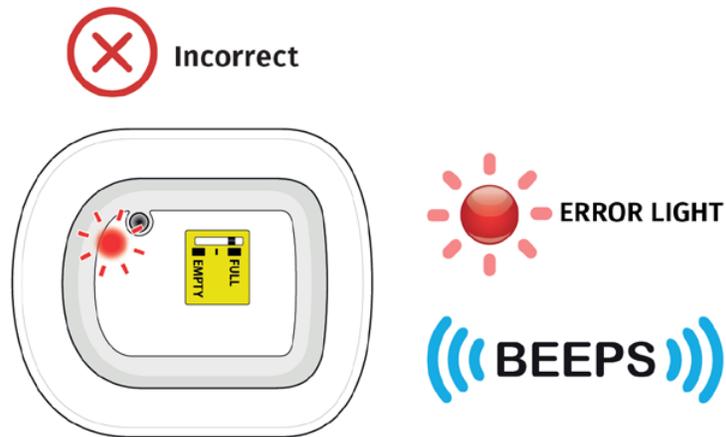


It is safe to remove the on-body injector after checking the following:

- The status light should be solid green.
- If the status light is flashing green, the dose delivery is not complete. Wait until you hear a long beep and the status light turns solid green before removing your on-body injector.
- The status light turns off 1 hour after delivery completion.
- The fill indicator should have a black line next to EMPTY.

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

- If the status light is flashing red, you may not have received your full dose and may need a replacement dose. Call your healthcare provider right away.



**What do I do if the on-body injector comes off before the full dose is delivered?**

Call your healthcare provider right away if the on-body injector at any time comes away from your skin before your full dose delivery, as you may need a replacement dose.

**Do not** reapply it. **Caution the needle may be exposed.** Dispose of the on-body injector into a sharps disposal container right away.

**What if there is blood at my application site after the on-body injector has been removed?**

If there is blood, press a clean cotton ball or gauze pad on the application site. Apply an adhesive bandage if needed.

**What if my application site is red or tender after on-body injector removal?**

Call your healthcare provider right away if you experience persistent or worsening redness or tenderness at the application site, as this can be a sign of infection.

**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-0215 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.

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

<b>The delivery system has been tested for Electromagnetic Immunity</b>		
<b>Immunity Test</b>	<b>IEC Test Level</b>	<b>Compliance Level</b>
<b>Electrostatic discharge (ESD) per IEC 61000-4-2</b>	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	±8 kV Contact ±15 kV Air
<b>Radiated RF EM fields per IEC 61000-4-3</b>	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
<b>Rated Power Frequency (50/60 Hz) magnetic fields per IEC 61000-4-8</b>	30 A/m	30 A/m
<b>Proximity magnetic fields per IEC 61000-4-39</b>	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	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240, 5500, 5785	5100 to 5800	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	
Part number	
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;	
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	

Description	Symbol/Sub clause
"Rx only" labeling of prescription devices	
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)	