INSTRUCTIONS FOR USE
UDENYCA® (yoo-den-i-ka)
(pegfilgrastim-cbqv)
injection, for subcutaneous use
Single-Dose Prefilled Autoinjector

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

Using the UDENYCA prefilled autoinjector
• It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
  • Only adults can self-inject UDENYCA with the prefilled autoinjector.
  • Make sure that the name UDENYCA appears on the carton and prefilled autoinjector label.
  • Check the carton and prefilled autoinjector 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 an UDENYCA prefilled autoinjector. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the UDENYCA prefilled autoinjector.
  • **Do not** use a prefilled autoinjector after the expiration date on the label.
  • **Do not** shake the prefilled autoinjector.
  • **Do not** remove the clear cap from the prefilled autoinjector until you are ready to inject.
  • **Do not** use the prefilled autoinjector if the carton is open or damaged.
  • **Do not** use a prefilled autoinjector if it has been dropped on a hard surface. The prefilled autoinjector may be broken even if you cannot see the break. Use a new prefilled autoinjector.

Call your healthcare provider if you have any questions.
Take the UDENYCA carton out of the refrigerator.
- Leave the prefilled autoinjector in the carton at room temperature for 30 minutes before injecting.
- **Do not** remove the clear cap while allowing the prefilled autoinjector to reach room temperature.
- **Do not** warm the prefilled autoinjector in any other way. For example, do not warm it in a microwave, in hot water, or in direct sunlight.

Check the expiration date on the prefilled autoinjector label. **Do not** use the prefilled autoinjector if the expiration date has passed. Place the following supplies on a clean, flat surface:
- 1 single-dose UDENYCA prefilled autoinjector
- 1 alcohol wipe (not included)
- 1 cotton ball or gauze pad (not included)
- 1 sharps disposal container (not included).

See "How should I throw away (dispose of) the used UDENYCA prefilled autoinjector?" in step 10.

Wash and dry your hands.
Choose an injection site.
• abdomen (except for a two-inch area surrounding the navel)
• thighs
If someone else is giving you the injection, you can also use the:
• back of upper arms
• upper outer area of the buttocks
• Do not inject into moles, scars, birthmarks, or areas where the skin is tender, bruised, red, or hard.
• Change (rotate) your injection site with each injection.
• Do not inject through clothing.
Clean the injection site with an alcohol wipe. Let your skin air dry. Do not touch this area again before injection.

Check the viewing window:
• Hold the prefilled autoinjector with the clear cap facing down.
• It is normal to see 1 or more air bubbles in the viewing window.
• Make sure the liquid is clear and colorless.
Do not use the prefilled autoinjector if:
• the medicine appears discolored or cloudy.
• the medicine contains lumps, flakes, or particles.
• if it has been dropped, crushed or damaged in any way.

Hold the prefilled autoinjector with the clear cap facing up and pull the clear cap straight off.
• It is normal to see a few drops of liquid at the end of the needle.
• Throw away the clear cap.
• Do not put the clear cap back on the prefilled autoinjector after it has been removed.
• Do not touch the gray needle guard.
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<td>6</td>
<td><strong>Hold</strong> the body of the prefilled autoinjector in one hand so you can see the viewing window. <strong>Place</strong> the gray needle guard against your skin at a 90-degree angle.</td>
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<td>7</td>
<td><strong>Press the prefilled autoinjector firmly</strong> against the skin and you will hear the first “click”. The orange indicator will start to move along the viewing window.</td>
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| 8    | **Keep holding the prefilled autoinjector firmly** against the skin until the orange indicator stops moving and you hear the second “click”.  
**After you hear the second “click”**, continue to hold the prefilled autoinjector in place and **count to 5**. When the injection is complete, make sure the orange indicator completely fills the viewing window before **slowly lifting the** prefilled autoinjector away from the skin. |
The gray needle guard will cover the needle tip. If the viewing window is not completely filled by the orange indicator or if there are more than a few drops of liquid on the injection site, contact your healthcare provider right away. You may not have received your full dose.

After completing the injection, place a cotton ball or gauze pad over the injection site.

- Do not rub the injection site.
- Slight bleeding at the injection site is normal.

How should I throw away (dispose of) the used UDENYCA prefilled autoinjector?

- Put your used prefilled autoinjector in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) prefilled autoinjectors in the 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 prefilled autoinjectors. 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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not reuse the prefilled autoinjector. Do not recycle your used sharps disposal container.

Important: Always keep the sharps disposal container out of reach of children.

- The clear cap, alcohol swab, cotton ball or gauze pad, and packaging may be placed in your household trash.