





























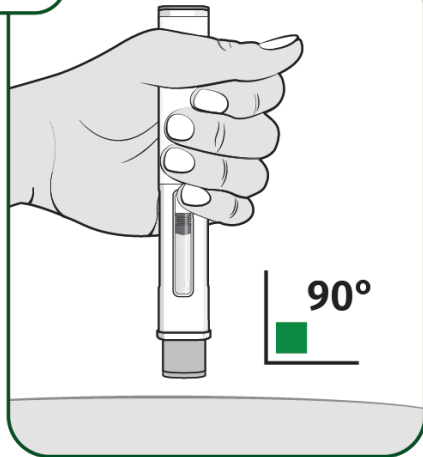






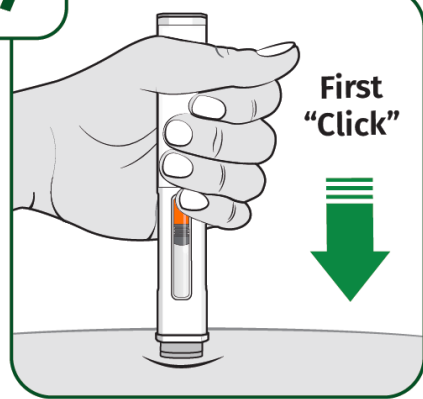


6



**Hold** the body of the prefilled autoinjector in one hand so you can see the viewing window. **Place** the gray needle guard against your skin at a 90-degree angle.

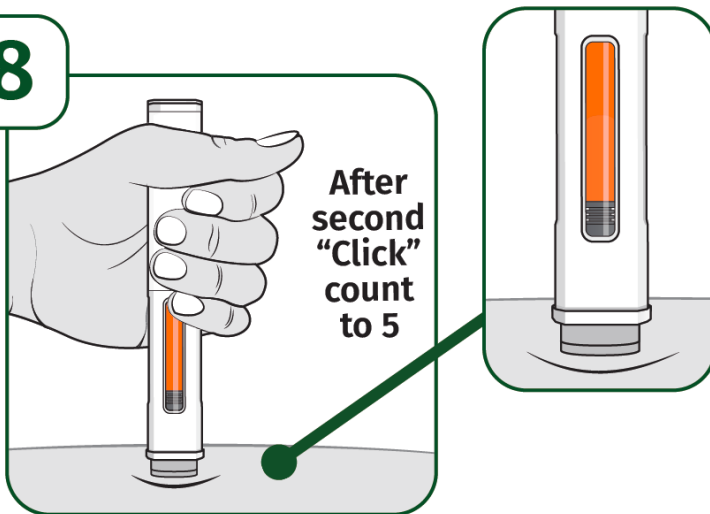
7



**Press the prefilled autoinjector firmly** against the skin and you will hear the **first “click”**.

The orange indicator will start to move along the viewing window.

8

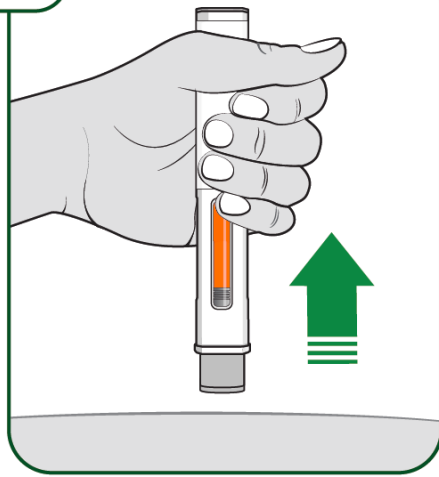


**Keep holding the prefilled autoinjector firmly** against the skin until the orange indicator stops moving and you hear the **second “click”**.

**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.

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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.

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**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

	<p>for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>.</p> <ul style="list-style-type: none"><li>• 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.</li></ul> <p><b>Important: Always keep the sharps disposal container out of reach of children.</b></p> <ul style="list-style-type: none"><li>• The clear cap, alcohol swab, cotton ball or gauze pad, and packaging may be placed in your household trash.</li></ul>
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Manufactured by Coherus BioSciences, Inc  
Redwood City, California 94065-1442  
US License Number: 2023

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

Issued: 03/2023

**Patient Information**  
UDENYCA® (yoo-den-i-kah)  
(pegfilgrastim-cbqv)  
injection

**What is UDENYCA?**

UDENYCA is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.

Acute Radiation Syndrome: The effectiveness of pegfilgrastim for this use was only studied in animals, because it could not be studied in people.

**Do not take UDENYCA** if you have had a serious allergic reaction to pegfilgrastim products or filgrastim products.

**Before you receive UDENYCA, tell your healthcare provider about all of your medical conditions, including if you:**

- have a sickle cell disorder.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if UDENYCA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if UDENYCA passes into your breast milk.

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How will I receive UDENYCA?**

- **UDENYCA is given as an injection under your skin (subcutaneous injection) by a healthcare provider. If your healthcare provider decides that the subcutaneous injections can be given at home by you or your caregiver, follow the detailed "Instructions for Use" that comes with your UDENYCA for information on how to prepare and inject a dose of UDENYCA.**
- You and your caregiver will be shown how to prepare and inject UDENYCA before you use it.
- UDENYCA comes in a prefilled syringe or a prefilled autoinjector. Your healthcare provider will prescribe the type of UDENYCA that is right for you.
- Only adults can self-inject UDENYCA with the prefilled autoinjector.
- You should not inject a dose of UDENYCA to children weighing less than 45 kg from a UDENYCA prefilled syringe or prefilled autoinjector. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the UDENYCA prefilled syringe or prefilled autoinjector.
- If you are receiving UDENYCA because you are also receiving chemotherapy, the last dose of UDENYCA should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of UDENYCA, talk to your healthcare provider about when you should give your next dose.
- When using the UDENYCA prefilled autoinjector:
  - You may miss your dose or may not receive your full dose if you lift the prefilled autoinjector before you hear the second "click" or if the orange indicator does not completely fill the viewing window.
  - Call your healthcare provider right away if this happens, as you may need a replacement dose of UDENYCA.

**What are possible side effects of UDENYCA?**

**UDENYCA may cause serious side effects, including:**

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach area or your left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** UDENYCA can cause serious allergic reactions. These reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you have any of these symptoms, stop using UDENYCA and call your healthcare provider or get emergency medical help right away.
- **Sickle cell crises.** You may have a serious sickle cell crisis, which could lead to death, if you have a sickle cell disorder and receive UDENYCA. Serious sickle cell crises have happened in people with sickle cell disorders receiving pegfilgrastim that has sometimes led to death. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** UDENYCA can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms:
  - swelling of your face or ankles
  - blood in your urine or dark colored urine
  - you urinate less than usual

- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with UDENYCA.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with UDENYCA. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with UDENYCA. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Capillary Leak Syndrome.** UDENYCA can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - swelling or puffiness and are urinating less than usual
  - trouble breathing
  - swelling of your stomach-area (abdomen) and feeling of fullness
  - dizziness or feeling faint
  - a general feeling of tiredness
- **Myelodysplastic syndrome and acute myeloid leukemia.** If you have breast cancer or lung cancer, when UDENYCA is used with chemotherapy and radiation therapy, or with radiation therapy alone, you may have an increased risk of developing a precancerous blood condition called myelodysplastic syndrome (MDS) or a blood cancer called acute myeloid leukemia (AML). Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding. Call your healthcare provider if you develop these symptoms during treatment with UDENYCA.
- **Inflammation of the aorta (aortitis).** Inflammation of the aorta (the large blood vessel that transports blood from the heart to the body) has been reported in patients who received pegfilgrastim. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

**The most common side effects of UDENYCA** are pain in the bones, arms, and legs.

These are not all the possible side effects of UDENYCA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store UDENYCA?**

- Store UDENYCA in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze. If UDENYCA is accidentally frozen, allow it to thaw in the refrigerator before injecting.
- **Do not** use UDENYCA that has been frozen more than 1 time. Use a new UDENYCA prefilled syringe or prefilled autoinjector.
- Throw away (dispose of) any UDENYCA that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 48 hours or frozen more than 1 time.
- Keep UDENYCA in the original carton to protect from light.
- Do not shake UDENYCA.
- Take UDENYCA out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.

**Keep UDENYCA out of the reach of children.**

#### **General information about the safe and effective use of UDENYCA.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use UDENYCA for a condition for which it was not prescribed. Do not give UDENYCA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about UDENYCA that is written for health professionals.

#### **What are the ingredients in UDENYCA?**

**Active ingredient:** pegfilgrastim-cbqv

**Inactive ingredients:** acetate, polysorbate 20, sodium, and sorbitol in Water for Injection.

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

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