

Patient Information

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

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.

Do not take UDENYCA if you have had a serious allergic reaction to pegfilgrastim 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.
- You should not inject a dose of UDENYCA to children weighing less than 45kg from a UDENYCA prefilled syringe. A dose less than 0.6 mL (6mg) cannot be accurately measured using the UDENYCA prefilled syringe.
- 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.

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 care 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 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.
- **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

- **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 the prefilled syringe to thaw in the refrigerator before injecting.
- **Do not** use a UDENYCA prefilled syringe that has been frozen more than 1 time. Use a new UDENYCA prefilled syringe.
- 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 the prefilled syringe in the original carton to protect from light.
- Do not shake the prefilled syringe.
- Take UDENYCA out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.

Keep the UDENYCA prefilled syringe 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, or call 1-800-4UDENYCA (1-800-483-3692)

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This Patient Information has been approved by the U.S. Food and Drug Administration

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