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 36ºF to 46ºF (2ºC to 8ºC).
- **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, 68ºF to 77ºF (20ºC to 25ºC), 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
U.S. License No. 2023

For more information, go to www.UDENYCA.com, or call 1-800-4UDENYCA (1-800-483-3692)
PMD-0006 Rev.06

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Patient Information
UDENYCA® (yoo-den-i-kah)
(pegfilgrastim-cbqv)
injection
on-body injector for UDENYCA

What is the most important information I need to know about receiving UDENYCA with the on-body injector for UDENYCA?

- **See the Instructions for Use for the on-body injector for UDENYCA for detailed information about the on-body injector for UDENYCA and important information about your dose delivery that has been written by your healthcare provider.**
  - Know the time that delivery of your dose of UDENYCA is expected to start.
  - Avoid traveling, driving, or operating heavy machinery during hour 26 through hour 29 after the on-body injector for UDENYCA is applied. Avoid activities and places that may interfere with monitoring during the **5-minute** period that UDENYCA is expected to be delivered by the on-body injector for UDENYCA, and for 1 hour after delivery.
- A caregiver should be with you the first time that you receive UDENYCA with the on-body injector for UDENYCA.
- Before your next scheduled UDENYCA dose, avoid use of lotions, creams, or oils on your arms and stomach area (abdomen) to help keep the device on your skin.
- If placed on the back of the arm, a caregiver must be available to monitor the status of the on-body injector.
- **If you have an allergic reaction during the delivery of UDENYCA, remove the on-body injector for UDENYCA by grabbing the edge of the adhesive pad and peeling off the on-body injector for UDENYCA. Get emergency medical help right away.**
- **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 fills and places the on-body injector for UDENYCA on your skin.
- **Do not** expose the on-body injector for UDENYCA to the following because the on-body injector for UDENYCA 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
- 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 for UDENYCA from being accidentally removed.
- **Keep the on-body injector for UDENYCA at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves and other common appliances.** If the on-body injector for UDENYCA is too close to electrical equipment, it may not work correctly and can lead to a missed or incomplete dose of UDENYCA.
- The on-body injector is for adult patients only.
- **If your on-body injector is not working properly, you may miss your dose or you may not receive your full dose of UDENYCA. If you miss your dose or do not receive your full dose of UDENYCA, you may have an increased risk of developing fever or infection.**
- **Call your healthcare provider right away, as you may need a replacement dose, if any of the following occur:**
  - on-body injector for UDENYCA comes off before or during a dose delivery. Do not re-apply it.
  - on-body injector for UDENYCA is leaking.
  - adhesive on your on-body injector for UDENYCA becomes noticeably wet (saturated) with fluid, or there is dripping. This may mean that UDENYCA is leaking out of your on-body injector for UDENYCA. If this happens you may only receive some of your dose of UDENYCA, or you may not receive a dose at all.
  - on-body injector for UDENYCA status light is flashing red.

What is UDENYCA?

UDENYCA is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid), who receive anti-cancer medicines (chemotherapy) that can cause fever and low blood cell count.

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 had severe skin reactions to acrylic adhesives.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if UDENYCA may 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?

See the Instructions for Use for detailed information about how you will receive a dose of UDENYCA with the on-body injector for UDENYCA, and how to remove and dispose of the on-body injector for UDENYCA.

- **See the section "What is the most important information I need to know about receiving UDENYCA with the on-body injector for UDENYCA?"**
- UDENYCA is given as an injection under the skin (subcutaneous). 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 for UDENYCA will be applied to the stomach area (abdomen) or back of your arm by your healthcare provider. If the on-body injector for UDENYCA was placed on the back of your arm, a caregiver must be available to monitor the on-body injector for UDENYCA.
- Your healthcare provider should place the on-body injector for UDENYCA on an area of your skin that does not have swelling, redness, cuts, wounds, or abrasions. Tell your healthcare provider about any skin reactions that happen in the on-body injector for UDENYCA application area after it has been applied.
- The on-body injector for UDENYCA is programmed to deliver your dose about 27 hours after your healthcare provider places the on-body injector for UDENYCA on your skin.
- The dose of UDENYCA will be delivered over about 5 minutes. During dose delivery and for 1 hour after delivery, it is best to stay in a place where you or a caregiver can monitor the on-body injector for UDENYCA to make sure you receive your full dose of UDENYCA and watch for symptoms of an allergic reaction.
- Your healthcare provider will show you how to monitor the on-body injector for UDENYCA to make sure delivery has been completed.
- Keep the on-body injector for UDENYCA dry for about the last 3 hours before the dose delivery is expected to start. This will help you to better detect possible leaking from the on-body injector for UDENYCA.
- Only expose the on-body injector for UDENYCA to temperatures between 41°F to 104°F (5°C to 40°C).

While the on-body injector for UDENYCA is in place you should avoid:

- traveling, driving, or operating heavy machinery during hour 26 through hour 29 after the on-body injector for UDENYCA is applied.
- sleeping on the on-body injector for UDENYCA or applying pressure on the on-body injector for UDENYCA. The on-body injector for UDENYCA may not work properly.
- bumping the on-body injector for UDENYCA or knocking it off your body.
- using other materials to hold the on-body injector in place. Using other materials could cover audio or visual indicators or press the on-body injector against your skin, and lead to a missed dose or incomplete dose of UDENYCA.
- getting body lotion, creams, oils, and skin cleansing products near the on-body injector for UDENYCA. These products may loosen the adhesive that holds the on-body injector for UDENYCA onto your body.
- using bathtubs, hot tubs, whirlpools, or saunas, and direct sunlight. These may affect UDENYCA.
- peeling off or disturbing the on-body injector for UDENYCA adhesive before you receive your full dose of UDENYCA.

What are the 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 your left upper stomach area or left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS)**. Call your healthcare provider or get emergency medical 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 an allergic reaction during the delivery of UDENYCA, remove the on-body injector for UDENYCA by grabbing the edge of the adhesive pad and peeling off the on-body injector for UDENYCA. 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. Call your healthcare provider right away if you develop 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 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 which transports blood from the heart to the body) has been reported in patients who received pegfilgrastim products. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

The most common side effect of UDENYCA is pain in your bones, and in your arms, and legs. These are not all the possible side effects of UDENYCA. For more information, ask your healthcare provider or pharmacist.

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

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. If you would like more information about UDENYCA, talk with your healthcare provider or pharmacist. You can ask your pharmacist 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
U.S. License No. 2023

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

Coherus BIOSCIENCES

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