On-the-go treatment injected

What is UDENYCA® (pegfilgrastim-cbqv)?

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.

UDENYCA ONBODY

On-body Injector for UDENYCA[®] pegfilgrastim-cboy

FMP

(pegfilgrastim-cbqv)

Injection 6 mg/0.6 mL

IMPORTANT SAFETY INFORMATION

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

UDENYCA® may help support your immune system while undergoing chemotherapy

Chemotherapy can **decrease** your white blood cell count

Chemotherapy can help stop cancer cells from growing, but it can also lower your white blood cell count. A low white blood cell count can put you at risk for infection and a complication called febrile neutropenia, which is serious and can delay your chemotherapy treatments.



UDENYCA **boosts** the growth of your white blood cells

UDENYCA increases your white blood cell count, which may help your body fight off infection and prevent febrile neutropenia.

The most common side effects of UDENYCA are bone pain, arm pain, and leg pain

These are not all of the possible side effects of UDENYCA. Please see the Important Safety Information throughout this brochure and contact your healthcare team for medical advice about side effects or concerns that you may have about your treatment. Together, you can decide on the best way to manage side effects so you can stay on track with your treatment.

IMPORTANT SAFETY INFORMATION

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.



How will I know if I have an infection?

Scan or click below to
VISIT UDENY(A,Com



for more information about your treatment

It's important to take your temperature

A fever is a sign of infection. Call your healthcare team immediately if you experience a fever of or higher than 100.4 °F (38.0 °C). Take your temperature any time you don't feel well or as recommended by your healthcare team. Other signs of infection include chills, shortness of breath, sore throat, stiff neck, and burning or pain with urination. Talk to your healthcare team about signs to look out for.

If you develop a fever, it is a medical emergency, and you must call your healthcare team immediately or go to the emergency room at your local hospital.

IMPORTANT SAFETY INFORMATION

What are possible side effects of UDENYCA? (continued)

- 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.







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 and see a flashing red light, call your healthcare provider immediately you may need a replacement dose.

IMPORTANT SAFETY INFORMATION

What are possible side effects of UDENYCA? (continued)

- Allergies to Acrylics (UDENYCA ONBODY™ only): The on-body injector (OBI) for UDENYCA uses acrylic adhesive. If you have had reactions to acrylic adhesives, use of this product may result in a significant reaction.
- 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



Steps you should know

On the day you receive chemo, your healthcare provider will apply your on-body injector.



with the on-body injector



The on-body injector delivers your medicine 27 hours after it is applied

Your healthcare provider will walk you through what to expect while wearing the device. **This quick guide can help you understand what to expect while wearing the on-body injector, but it does not replace the enclosed Instructions for Use. Please refer to it while wearing the on-body injector.** Talk to your healthcare provider or pharmacist if you have any questions.

Note: After your provider applies the on-body injector, keep it dry for the next 3 hours. This is to ensure proper adhesion and functionality of the device.

While wearing your on-body injector



MONITOR YOUR ON-BODY INJECTOR

Occasionally, check the status light for at least 10 seconds. **Confirm it's flashing green.** If applied on the back of your arm, a caregiver must be available to check.

ENSURE THE ON-BODY INJECTOR IS DRY FOR 3 HOURS BEFORE DOSE DELIVERY.

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OBSERVE THE INJECTION

Before your injection begins, the on-body injector needle will automatically insert into your skin.

During the injection, the on-body injector will flash a fast, green light, and you may hear the pump working. It will take just **5 minutes** for your dose of UDENYCA to be delivered.



CONFIRM INJECTION IS COMPLETE

When the injection is complete, a long beep will sound, and the status light will turn solid green.

Confirm your injection is complete by checking to see if status light is solid green or has switched off.



ENSURE YOUR ON-BODY INJECTOR IS EMPTY

Grasp the edge of the adhesive and slowly peel the device off. Do not grab the on-body injector to pull it off of your body.

Check to see if your on-body injector is empty. You should see a black line next to the **empty** indicator.

If you hear beeping at any time, check the status light. If it is flashing red, call your healthcare provider right away.

Please see additional Important Safety Information throughout this brochure and click for the <u>Patient Information</u>, <u>Prescribing Information</u>, and <u>Instructions for Use</u>.



27

The UDENYCA on-body injector may be right for you if you:



IMPORTANT SAFETY INFORMATION

What are possible side effects of UDENYCA? (continued)

- 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.



The dos and don'ts of using the on-body injector





To ensure the proper use of your on-body injector and to achieve the best possible outcomes with UDENYCA, please follow these guidelines:

DO

- Be careful not to bump the on-body injector or knock the on-body injector off your body.
- WEAR THE ON-BODY INJECTOR UNDER CLOTHING. Ensure the on-body injector is protected from direct sunlight. If it is exposed to sunlight for more than 1 hour, it may affect your medication.
- CHECK THE STATUS LIGHT REGULARLY.
- CHECK YOUR ON-BODY INJECTOR OFTEN FOR LEAKS during the 5-minute dose delivery. After 5 minutes, check to see if your on-body injector is empty.
- AFTER SHOWERING, check the on-body injector to make sure it has not become loose or dislodged.
- ALWAYS KEEP THE ON-BODY INJECTOR AT LEAST 4 INCHES AWAY from electrical equipment such as cell phones, cordless telephones, microwaves, and other common appliances.

DON'T

- DO NOT PEEL OFF OR DISTURB THE ON-BODY INJECTOR ADHESIVE before your full dose is complete. Interrupting the on-body injector before the dose is complete may result in a missed or incomplete dose of UDENYCA.
- O NOT REMOVE THE ON-BODY INJECTOR IF THE STATUS LIGHT IS FLASHING GREEN. The on-body injector is still working properly, and your dose is not yet complete.
- DO NOT EXPOSE to diagnostic imaging (eg, CT scan, MRI, Ultrasound, X-ray), radiation treatment, or oxygen-rich environments (such as hyperbaric chambers).
- DO NOT ALLOW LOTIONS, CREAMS, OILS, OR CLEANING AGENTS to come into contact with the on-body injector at any time. The day before your next UDENYCA dose, avoid using lotions, creams, and oils on the area where the injector will be attached.
- **DO NOT USE** bathtubs, hot tubs, whirlpools, or saunas while wearing the on-body injector. This may affect your medicine and delivery.
- DO NOT SLEEP ON OR APPLY PRESSURE to the on-body injector during wear, especially during dose delivery. This may affect the on-body injector performance.

Please refer to the Patient <u>Instructions for Use</u> for additional details regarding dos and don'ts when wearing your on-body injector, and please see Important Safety Information throughout this brochure.





To be completed by your healthcare provider after you receive the UDENYCA on-body injector

On-body injector was applied at:

Injection of your dose will start around:

If you have questions, call us at:

IMPORTANT SAFETY INFORMATION

What are possible side effects of UDENYCA? (continued)

- **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



Working together to ensure patient access

Financial support is available

UDENYCA Solutions[™], part of Coherus Solutions[™], provides financial support options for eligible patients prescribed UDENYCA. Ask your doctor's office for help applying.



FIND MORE DETAILS

Scan or click <u>here</u> for support and eligibility, or call **1-844-4-UDENYCA** (1-844-483-3692).

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.

- **Bone Imaging (Nuclear Imaging):** The formation of certain blood cells may increase and can be associated with short term changes in bone imaging. Your doctor should consider this when interpreting bone imaging results.
- Allergies to Acrylics (UDENYCA ONBODY only): The on-body injector (OBI) for UDENYCA uses acrylic adhesive. If you have had reactions to acrylic adhesives, use of this product may result in a significant reaction.

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 healthcare provider for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences at 1-800-4-UDENYCA (1-800-483-3692) or notify the FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

Please click for the <u>Patient Information</u> and <u>Prescribing Information</u> for UDENYCA.



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