HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use UDENYCA safely and effectively. See full prescribing information for UDENYCA.

UDENYCA® (pegfilgrastim-cbqv) injection, for subcutaneous use

INITIAL U.S. APPROVAL: 2018

UDENYCA (pegfilgrastim-cbqv) is biosimilar* to NEULASTA (pegfilgrastim).

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.2) and (2.3) 12/2023

----------INDICATIONS AND USAGE----------

UDENYCA is a leukocyte growth factor indicated to

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. (1.1)
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome). (1.2)

Limitations of Use

UDENYCA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation**.**

----------DOSAGE AND ADMINISTRATION----------

- Patients with cancer receiving myelosuppressive chemotherapy
  - 6 mg administered subcutaneously once per chemotherapy cycle. (2.1)
  - Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy. (2.1)
  - Use weight based dosing for pediatric patients weighing less than 45 kg; refer to Table 1. (2.3)
- Patients acutely exposed to myelosuppressive doses of radiation
  - Two doses, 6 mg each, administered subcutaneously one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after. (2.2)
  - Use weight based dosing for pediatric patients weighing less than 45 kg; refer to Table 1. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

Injection:

- 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only. (3)
- 6 mg/0.6 mL in a single-dose prefilled autoinjector. (3)
- 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the on-body injector for UDENYCA. (3)

----------CONTRAINDICATIONS----------

Patients with a history of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim products or filgrastim products. (4)

----------WARNINGS AND PRECAUTIONS----------

- Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture (5.1)
- Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA in patients with ARDS. (5.2)
- Serious allergic reactions, including anaphylaxis: Permanently discontinue UDENYCA in patients with serious allergic reactions. (5.3)
- The on-body injector for UDENYCA uses acrylic adhesives. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction. (5.4)
- Fatal sickle cell crises: Discontinue UDENYCA if sickle cell crisis occurs. (5.5)
- Glomerulonephritis: Evaluate and consider dose-reduction or interruption of UDENYCA if causality is likely. (5.6)
- Thrombocytopenia: Monitor platelet count (5.8)
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using UDENYCA in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML. (5.11)
- Potential device failures: Instruct patients to notify their healthcare provider if they suspect the on-body injector may not have performed as intended. (5.12)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Accord BioPharma, Inc. at 1-866-941-7875 or FDA at 1-800-FDA-1088 (1-800-332-1088) or *www.fda.gov/medwatch*

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

* Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of UDENYCA has been demonstrated for the condition(s) of use (e.g. indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Revised: 07/2025

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

UDENYCA is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia *[see Clinical Studies (14.1)]*.

Limitations of Use

UDENYCA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

1.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

UDENYCA is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation *[see Dosage and Administration (2.2) and Clinical Studies (14.2)].*

2 DOSAGE AND ADMINISTRATION

2.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

The recommended dosage of UDENYCA is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. For dosing in pediatric patients weighing less than 45 kg, refer to Table 1. Do not administer UDENYCA between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

2.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

The recommended dose of UDENYCA is two doses, 6 mg each, administered subcutaneously one week apart. For dosing in pediatric patients weighing less than 45 kg, refer to Table 1. Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose.

Obtain a baseline complete blood count (CBC). Do not delay administration of UDENYCA if a CBC is not readily available. Estimate a patient's absorbed radiation dose (i.e., level of radiation exposure) based on information from public health authorities, biodosimetry if available, or clinical findings such as time to onset of vomiting or lymphocyte depletion kinetics.

2.3 Administration

UDENYCA is administered subcutaneously via a single-dose prefilled autoinjector, a single-dose prefilled syringe for manual use or for use with the on-body injector (OBI) for UDENYCA, which is co-packaged with a single dose prefilled syringe for OBI. Use of the OBI for UDENYCA is not recommended for patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome. Use of the OBI has not been studied in pediatric patients.

Prior to use, remove the carton from the refrigerator and allow UDENYCA to reach room temperature for a minimum of 30 minutes. Discard any UDENYCA left at room temperature for greater than 48 hours.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer UDENYCA if discoloration or particulates are observed.

The needle cap on the prefilled syringe and prefilled autoinjector is not made with natural rubber latex.

Pediatric Patients Weighing Less than 45 kg

The UDENYCA prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks which are necessary to accurately measure doses of UDENYCA less than 0.6 mL (6 mg) for direct administration to patients. Thus, the direct administration to patients requiring dosing of less than 0.6 mL (6 mg) is not recommended due to the potential for dosing errors. Refer to Table 1.

Table 1. Dosing of UDENYCA for pediatric patients weighing less than 45 kg

Body Weight	UDENYCA Dose	Volume to Administer
Less than 10 kg*	See below*	See below*
10 – 20 kg	1.5 mg	0.15 mL
21 – 30 kg	2.5 mg	0.25 mL
31 – 44 kg	4 mg	0.4 mL

*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of UDENYCA

The UDENYCA prefilled autoinjector is not suitable for use in pediatric patients weighing less than 45 kg. The UDENYCA prefilled autoinjector delivers the entire contents (6 mg in 0.6 mL) in a single injection and is not adjustable.

2.4 Advice to Give to Patients or Caregivers Regarding Administration via the Prefilled Autoinjector

Only adults can self-administer UDENYCA with the prefilled autoinjector. If subcutaneous injections can be given at home, refer the patient or caregiver to the dose delivery information provided in the Instructions for Use. Provide training to patients or caregivers to ensure they understand how to administer UDENYCA via the prefilled autoinjector. Ensure patients or caregivers understand how to identify that a full dose has been administered by listening for the second 'click' and checking that the 'Orange Indicator' completely blocks the viewing window. Instruct patients or caregivers using the prefilled autoinjector to notify their healthcare provider immediately in order to determine the need for a replacement dose of UDENYCA if they suspect that the full dose may not have been administered.

2.5 Special Healthcare Provider Instructions for the On-body Injector for UDENYCA

A healthcare provider must fill the on-body injector (OBI) with UDENYCA using the prefilled syringe and then apply the OBI for UDENYCA to the patient's skin (abdomen or back of arm). The back of the arm may only be used if there is a caregiver available to monitor the status of the OBI for UDENYCA. Approximately 27 hours after the OBI for UDENYCA is applied to the patient's skin, UDENYCA will be delivered over approximately 5 minutes. A healthcare provider may initiate administration with the OBI for UDENYCA on the same day as the administration of cytotoxic chemotherapy, as long as the OBI for UDENYCA delivers UDENYCA no less than 24 hours after administration of cytotoxic chemotherapy.

The prefilled syringe co-packaged in UDENYCA ONBODY must only be used with the OBI for UDENYCA. The prefilled syringe contains additional solution to compensate for liquid loss during filling of the OBI and delivery through the OBI for UDENYCA. If the prefilled syringe co-packaged in UDENYCA ONBODY is used for manual subcutaneous injection, the patient will receive an overdose. If the single-dose prefilled syringe for manual use is used with the OBI for UDENYCA, the patient may receive less than the recommended dose.

Do not use the OBI for UDENYCA to deliver any other drug product except the UDENYCA prefilled syringe co-packaged with the OBI for UDENYCA.

The OBI for UDENYCA should be applied to intact, non-irritated skin on the arm or abdomen.

A missed dose could occur due to an OBI for UDENYCA failure or leakage. If the patient misses a dose, a new dose should be administered by single-dose prefilled syringe for manual use, as soon as possible after detection.

Refer to the Healthcare Provider Instructions for Use for the OBI for UDENYCA for full administration information.

2.6 Advice to give to Patients Regarding Administration via the On-body Injector for UDENYCA

Advise patients to avoid activities such as traveling, driving, or operating heavy machinery during hours 26-29 following application of the on-body injector (OBI) for UDENYCA (this includes the 5-minute delivery period plus an hour post-delivery). Patients should have a caregiver nearby for the first use.

Refer the patient to the dose delivery information written on the Patient Instructions for Use. Provide training to patients to ensure they understand when the dose delivery of UDENYCA will begin and how to monitor the OBI for UDENYCA for completed delivery. Ensure patients understand how to identify signs of malfunction of OBI for

UDENYCA *[see Warnings and Precautions (5.12) and Patient Counseling Information (17)]*. Instruct patients using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of UDENYCA if they suspect that the device may not have performed as intended *[see Warnings and Precautions (5.12)]*.

3 DOSAGE FORMS AND STRENGTHS

UDENYCA is a clear, colorless, preservative free solution available as:

- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.
- Injection: 6 mg/0.6 mL in a single-dose prefilled autoinjector.
- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the on-body injector (OBI) for UDENYCA (UDENYCA ONBODY).

4 CONTRAINDICATIONS

UDENYCA is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products. Reactions have included anaphylaxis *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving UDENYCA.

5.2 Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) can occur in patients receiving pegfilgrastim products. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving UDENYCA for ARDS. Discontinue UDENYCA in patients with ARDS.

5.3 Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue UDENYCA in patients with serious allergic reactions. Do not administer UDENYCA to patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products.

5.4 Allergies to Acrylics

The on-body injector (OBI) for UDENYCA uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.

5.5 Use in Patients with Sickle Cell Disorders

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products. Discontinue UDENYCA if sickle cell crisis occurs.

5.6 Glomerulonephritis

Glomerulonephritis has occurred in patients receiving pegfilgrastim products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose reduction or discontinuation of pegfilgrastim products. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of UDENYCA.

5.7 Leukocytosis

White blood cell (WBC) counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim products. Monitoring of complete blood count (CBC) during UDENYCA therapy is recommended.

5.8 Thrombocytopenia

Thrombocytopenia has been reported in patients receiving pegfilgrastim products. Monitor platelet counts.

5.9 Capillary Leak Syndrome

Capillary leak syndrome has been reported after G-CSF administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

5.10 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which pegfilgrastim products and filgrastim products act has been found on tumor cell lines. The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.

5.11 Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

MDS and AML have been associated with the use of pegfilgrastim products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

5.12 Potential Device failures

Missed or partial doses have been reported in patients receiving UDENYCA via the on-body injector (OBI) due to the device not performing as intended. In the event of a missed or partial dose, patients may be at increased risk of events such as neutropenia, febrile neutropenia and/or infection than if the dose had been correctly delivered.

Instruct patients using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of UDENYCA if they suspect that the device may not have performed as intended.

5.13 Aortitis

Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue UDENYCA if aortitis is suspected.

5.14 Nuclear Imaging

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Splenic Rupture *[see Warnings and Precautions (5.1)]*
- Acute Respiratory Distress Syndrome *[see Warnings and Precautions (5.2)]*
- Serious Allergic Reactions *[see Warnings and Precautions (5.3)]*
- Allergies to Acrylics *[see Warnings and Precautions (5.4)]*

- Use in Patients with Sickle Cell Disorders *[see Warnings and Precautions (5.5)]*
- Glomerulonephritis *[see Warnings and Precautions (5.6)]*
- Leukocytosis *[see Warnings and Precautions (5.7)]*
- Thrombocytopenia *[see Warnings and Precautions (5.8)]*
- Capillary Leak Syndrome *[see Warnings and Precautions (5.9)]*
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells *[see Warnings and Precautions (5.10)]*
- Myelodysplastic syndrome *[see Warnings and Precautions (5.11)]*
- Acute myeloid leukemia *[see Warnings and Precautions (5.11)]*
- Aortitis *[see Warnings and Precautions (5.13)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Pegfilgrastim clinical trials safety data are based upon 932 patients receiving pegfilgrastim in seven randomized clinical trials. The population was 21 to 88 years of age and 92% female. The ethnicity was 75% Caucasian, 18% Hispanic, 5% Black, and 1% Asian. Patients with breast (n = 823), lung and thoracic tumors (n = 53) and lymphoma (n = 56) received pegfilgrastim after nonmyeloablative cytotoxic chemotherapy. Most patients received a single 100 mcg/kg (n = 259) or a single 6 mg (n = 546) dose per chemotherapy cycle over 4 cycles.

The following adverse reaction data in Table 2 are from a randomized, double-blind, placebo-controlled study in patients with metastatic or non-metastatic breast cancer receiving docetaxel 100 mg/m^2 every 21 days (Study 3). A total of 928 patients were randomized to receive either 6 mg pegfilgrastim (n = 467) or placebo (n = 461). The patients were 21 to 88 years of age and 99% female. The ethnicity was 66% Caucasian, 31% Hispanic, 2% Black, and <1% Asian, Native American or other.

The most common adverse reactions occurring in ≥ 5% of patients and with a between-group difference of ≥ 5% higher in the pegfilgrastim arm in placebo controlled clinical trials are bone pain and pain in extremity.

Table 2. Adverse Reactions with ≥ 5% Higher Incidence in pegfilgrastim Patients Compared to Placebo in Study 3

Body System **Adverse Reaction**	**Placebo** **(N = 461)**	**pegfilgrastim 6 mg SC on Day 2** **(N = 467)**
Musculoskeletal and connective tissue disorders		
Bone Pain	26%	31%
Pain in Extremity	4%	9%

Leukocytosis

In clinical studies, leukocytosis (WBC counts > 100 x 10^9/L) was observed in less than 1% of 932 patients with non-myeloid malignancies receiving pegfilgrastim. No complications attributable to leukocytosis were reported in clinical studies.

6.2 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of pegfilgrastim or of other pegfilgrastim products.

Binding antibodies to pegfilgrastim were detected using a BIAcore assay. The approximate limit of detection for this assay is 500 ng/mL. Pre-existing binding antibodies were detected in approximately 6% (51/849) of patients with metastatic breast cancer. Four of 521 pegfilgrastim-treated subjects who were negative at baseline developed binding antibodies to pegfilgrastim following treatment. None of these 4 patients had evidence of neutralizing antibodies detected using a cell-based bioassay.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post approval use of pegfilgrastim products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Splenic rupture and splenomegaly (enlarged spleen) *[see Warnings and Precautions (5.1)]*
- Acute respiratory distress syndrome (ARDS) *[see Warnings and Precautions (5.2)]*
- Allergic reactions/hypersensitivity, including anaphylaxis, skin rash, urticaria, generalized erythema and flushing *[see Warnings and Precautions (5.3)]*
- Sickle cell crisis *[see Warnings and Precautions (5.5)]*
- Glomerulonephritis *[see Warnings and Precautions (5.6)]*
- Leukocytosis *[see Warnings and Precautions (5.7)]*
- Thrombocytopenia *[see Warnings and Precautions (5.8)]*
- Capillary leak syndrome *[see Warnings and Precautions (5.9)]*
- Injection site reactions
- Sweet's syndrome *(acute febrile neutrophilic dermatosis),* cutaneous vasculitis
- Application site reactions (including events such as application site hemorrhage, application site pain, application site discomfort, application site bruise, and application site erythema) have been reported with the use of the on-body-injector for UDENYCA.
- Contact dermatitis and local skin reactions such as rash, pruritus, and urticaria have been reported with the use of the on-body-injector for UDENYCA, possibly indicating a hypersensitivity reaction to the adhesive.
- Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in patients with breast and lung cancer receiving chemotherapy and/or radiotherapy *[see Warnings and Precautions (5.11)]*
- Aortitis *[see Warnings and Precautions (5.13)]*
- Alveolar hemorrhage

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Although available data with UDENYCA or pegfilgrastim product use in pregnant women are insufficient to establish whether there is a drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes, there are available data from published studies in pregnant women exposed to filgrastim products. These studies have not established an association of filgrastim product use during pregnancy with major birth defects, miscarriage, or adverse maternal or fetal outcomes.

In animal studies, no evidence of reproductive/developmental toxicity occurred in the offspring of pregnant rats that received cumulative doses of pegfilgrastim approximately 10 times the recommended human dose (based on body surface area). In pregnant rabbits, increased embryo lethality and spontaneous abortions occurred at 4 times the maximum recommended human dose simultaneously with signs of maternal toxicity (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Pregnant rabbits were dosed with pegfilgrastim subcutaneously every other day during the period of organogenesis. At cumulative doses ranging from the approximate human dose to approximately 4 times the recommended human dose (based on body surface area), the treated rabbits exhibited decreased maternal food consumption, maternal weight loss, as well as reduced fetal body weights and delayed ossification of the fetal skull; however, no structural anomalies were observed in the offspring from either study. Increased incidences of post-implantation losses and spontaneous abortions (more than half the pregnancies) were observed at cumulative doses approximately 4 times

the recommended human dose, which were not seen when pregnant rabbits were exposed to the recommended human dose.

Three studies were conducted in pregnant rats dosed with pegfilgrastim at cumulative doses up to approximately 10 times the recommended human dose at the following stages of gestation: during the period of organogenesis, from mating through the first half of pregnancy, and from the first trimester through delivery and lactation. No evidence of fetal loss or structural malformations was observed in any study. Cumulative doses equivalent to approximately 3 and 10 times the recommended human dose resulted in transient evidence of wavy ribs in fetuses of treated mothers (detected at the end of gestation but no longer present in pups evaluated at the end of lactation).

8.2 Lactation

Risk Summary

There are no data on the presence of pegfilgrastim products in human milk, the effects on the breastfed child, or the effects on milk production. Other filgrastim products are secreted poorly into breast milk, and filgrastim products are not absorbed orally by neonates. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for UDENYCA and any potential adverse effects on the breastfed child from UDENYCA or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of UDENYCA have been established in pediatric patients. No overall differences in safety were identified between adult and pediatric patients based on postmarketing surveillance and review of the scientific literature.

Use of UDENYCA in pediatric patients for chemotherapy-induced neutropenia is based on UDENYCA's approval as a biosimilar to pegfilgrastim and evidence from adequate and well controlled studies of pegfilgrastim in adults with additional pharmacokinetic and safety data of pegfilgrastim in pediatric patients with sarcoma *[see Clinical Pharmacology (12.3) and Clinical Studies (14.1)]*.

The use of UDENYCA to increase survival in pediatric patients acutely exposed to myelosuppressive doses of radiation is based on UDENYCA's approval as a biosimilar to pegfilgrastim and evidence from efficacy studies of pegfilgrastim conducted in animals and clinical data supporting the use of pegfilgrastim in patients with cancer receiving myelosuppressive chemotherapy. Efficacy studies of pegfilgrastim products could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Results from population modeling and simulation indicate that two doses of pegfilgrastim (Table 1), administered one week apart provide pediatric patients with exposures comparable to that in adults receiving two 6 mg doses one week apart *[see Dosage and Administration (2.3), Clinical Pharmacology (12.3) and Clinical Studies (14.2)].*

8.5 Geriatric Use

Of the 932 patients with cancer who received pegfilgrastim in clinical studies, 139 (15%) were age 65 and over, and 18 (2%) were age 75 and over. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

10 OVERDOSAGE

Overdosage of pegfilgrastim products may result in leukocytosis and bone pain. Events of edema, dyspnea, and pleural effusion have been reported in a single patient who administered pegfilgrastim on 8 consecutive days in error. In the event of overdose, the patient should be monitored for adverse reactions *[see Adverse Reactions (6)]*.

11 DESCRIPTION

Pegfilgrastim-cbqv is a covalent conjugate of recombinant methionyl human G-CSF and monomethoxypolyethylene glycol. Recombinant methionyl human G-CSF is a water-soluble, 175 amino acid protein with a molecular weight of approximately 19 kilodaltons (kDa). Recombinant methionyl human G-CSF is obtained from the bacterial fermentation of a strain of *E coli* transformed with a genetically engineered plasmid containing the human G-CSF gene. During the pegfilgrastim-cbqv manufacturing process, fermentation is carried out in nutrient medium containing the antibiotic kanamycin. However, kanamycin is cleared in the manufacturing process and is not

detectable in the final product. To produce pegfilgrastim-cbqv, a 20 kDa monomethoxypolyethylene glycol molecule is covalently bound to the N-terminal methionyl residue of recombinant methionyl human G-CSF. The average molecular weight of pegfilgrastim-cbqv is approximately 39 kDa.

UDENYCA (pegfilgrastim-cbqv) injection is provided in three presentations:

- UDENYCA for manual subcutaneous injection is supplied in 0.6 mL prefilled syringes. The prefilled syringe does not bear graduation marks and is designed to deliver the entire contents of the syringe (6 mg/0.6 mL).
- UDENYCA for subcutaneous injection is supplied in a 0.6 mL prefilled single-dose autoinjector. The prefilled autoinjector delivers the entire contents (6 mg in 0.6 mL) in a single injection and is not adjustable.
- On-body injector (OBI) for UDENYCA is supplied with a prefilled syringe containing 0.67 mL of UDENYCA in solution that delivers 0.6 mL of UDENYCA in solution when used with the OBI for UDENYCA. The syringe does not bear graduation marks and is only to be used with the OBI for UDENYCA.

The delivered 0.6 mL dose from either the prefilled syringe for manual subcutaneous injection, the prefilled autoinjector or the OBI for UDENYCA contains 6 mg pegfilgrastim-cbqv (based on protein weight) in a sterile, clear, colorless, preservative-free solution (pH 4.0) containing acetate (0.35 mg), polysorbate 20 (0.02 mg), sodium (0.02 mg), and sorbitol (30 mg) in Water for Injection, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

12.2 Pharmacodynamics

Animal data and clinical data in humans suggest a correlation between pegfilgrastim products exposure and the duration of severe neutropenia as a predictor of efficacy. Selection of the dosing regimen of UDENYCA is based on reducing the duration of severe neutropenia.

12.3 Pharmacokinetics

The pharmacokinetics of pegfilgrastim were studied in 379 patients with cancer. The pharmacokinetics of pegfilgrastim were nonlinear, and clearance decreased with increases in dose. Neutrophil receptor binding is an important component of the clearance of pegfilgrastim, and serum clearance is directly related to the number of neutrophils. In addition to numbers of neutrophils, body weight appeared to be a factor. Patients with higher body weights experienced higher systemic exposure to pegfilgrastim after receiving a dose normalized for body weight. A large variability in the pharmacokinetics of pegfilgrastim was observed. The half-life of pegfilgrastim ranged from 15 to 80 hours after subcutaneous injection. In healthy volunteers, the pharmacokinetics of pegfilgrastim were comparable when delivered subcutaneously via a manual prefilled syringe versus via the on-body-injector (OBI) for UDENYCA.

Specific Populations

No gender-related differences were observed in the pharmacokinetics of pegfilgrastim, and no differences were observed in the pharmacokinetics of geriatric patients (≥ 65 years of age) compared with younger patients (< 65 years of age) *[see Use in Specific Populations (8.5)]*.

Renal Impairment

In a study of 30 subjects with varying degrees of renal dysfunction, including end stage renal disease, renal dysfunction had no effect on the pharmacokinetics of pegfilgrastim.

Pediatric Patients with Cancer Receiving Myelosuppressive Chemotherapy

The pharmacokinetics and safety of pegfilgrastim were studied in 37 pediatric patients with sarcoma in Study 4 *[see Clinical Studies 14.1]*. The mean (± standard deviation [SD]) systemic exposure ($AUC_{0\text{-}inf}$) of pegfilgrastim after subcutaneous administration at 100 mcg/kg was 47.9 (± 22.5) mcg·hr/mL in the youngest age group (0 to 5 years, n = 11), 22.0 (± 13.1) mcg·hr/mL in the 6 to 11 years age group (n = 10), and 29.3 (± 23.2) mcg·hr/mL in

the 12 to 21 years age group (n = 13). The terminal elimination half-lives of the corresponding age groups were 30.1 (± 38.2) hours, 20.2 (± 11.3) hours, and 21.2 (± 16.0) hours, respectively.

Patients Acutely Exposed to Myelosuppressive Doses of Radiation

The pharmacokinetics of pegfilgrastim is not available in patients acutely exposed to myelosuppressive doses of radiation. Based on limited pharmacokinetic data in irradiated non-human primates, the area under the concentration-time curve (AUC), reflecting the exposure to pegfilgrastim in non-human primates following a 300 mcg/kg dose of pegfilgrastim, appears to be greater than in humans receiving a 6 mg dose. Results from population modeling and simulation indicate that two 6 mg doses of pegfilgrastim administered one week apart in adults result in clinically relevant effects on duration of grade 3 and 4 neutropenia. In addition, weight-based dosing in pediatric patients weighing less than 45 kg *[see Dosage and Administration, Section 2.3, Table 1]* provides exposures comparable to those in adults receiving two 6 mg doses one week apart.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenesis studies have been performed with pegfilgrastim products.

Pegfilgrastim did not affect reproductive performance or fertility in male or female rats at cumulative weekly doses approximately 6 to 9 times higher than the recommended human dose (based on body surface area).

14 CLINICAL STUDIES

14.1 Patients with Cancer Receiving Myelosuppressive Chemotherapy

Pegfilgrastim was evaluated in three randomized, double-blind, controlled studies. Studies 1 and 2 were active-controlled studies that employed doxorubicin 60 mg/m^2 and docetaxel 75 mg/m^2 administered every 21 days for up to 4 cycles for the treatment of metastatic breast cancer. Study 1 investigated the utility of a fixed dose of pegfilgrastim. Study 2 employed a weight-adjusted dose. In the absence of growth factor support, similar chemotherapy regimens have been reported to result in a 100% incidence of severe neutropenia (ANC < 0.5 x 10^9/L) with a mean duration of 5 to 7 days and a 30% to 40% incidence of febrile neutropenia. Based on the correlation between the duration of severe neutropenia and the incidence of febrile neutropenia found in studies with filgrastim, duration of severe neutropenia was chosen as the primary endpoint in both studies, and the efficacy of pegfilgrastim was demonstrated by establishing comparability to filgrastim-treated patients in the mean days of severe neutropenia.

In Study 1, 157 patients were randomized to receive a single subcutaneous injection of pegfilgrastim (6 mg) on day 2 of each chemotherapy cycle or daily subcutaneous filgrastim (5 mcg/kg/day) beginning on day 2 of each chemotherapy cycle. In Study 2, 310 patients were randomized to receive a single subcutaneous injection of pegfilgrastim (100 mcg/kg) on day 2 or daily subcutaneous filgrastim (5 mcg/kg/day) beginning on day 2 of each chemotherapy cycle.

Both studies met the major efficacy outcome measure of demonstrating that the mean days of severe neutropenia of pegfilgrastim-treated patients did not exceed that of filgrastim-treated patients by more than 1 day in cycle 1 of chemotherapy. The mean days of cycle 1 severe neutropenia in Study 1 were 1.8 days in the pegfilgrastim arm compared to 1.6 days in the filgrastim arm [difference in means 0.2 (95% CI -0.2, 0.6)] and in Study 2 were 1.7 days in the pegfilgrastim arm compared to 1.6 days in the filgrastim arm [difference in means 0.1 (95% CI -0.2, 0.4)].

A secondary endpoint in both studies was days of severe neutropenia in cycles 2 through 4 with results similar to those for cycle 1.

Study 3 was a randomized, double-blind, placebo-controlled study that employed docetaxel 100 mg/m^2 administered every 21 days for up to 4 cycles for the treatment of metastatic or non-metastatic breast cancer. In this study, 928 patients were randomized to receive a single subcutaneous injection of pegfilgrastim (6 mg) or placebo on day 2 of each chemotherapy cycle. Study 3 met the major trial outcome measure of demonstrating that the incidence of febrile neutropenia (defined as temperature ≥ 38.2°C and ANC ≤ 0.5 x10^9/L) was lower for pegfilgrastim-treated patients as compared to placebo-treated patients (1% versus 17%, respectively, p < 0.001). The incidence of hospitalizations (1% versus 14%) and IV anti-infective use (2% versus 10%) for the treatment of febrile neutropenia was also lower in the pegfilgrastim-treated patients compared to the placebo-treated patients.

Study 4 was a multicenter, randomized, open-label study to evaluate the efficacy, safety, and pharmacokinetics *[see Clinical Pharmacology (12.3)]* of pegfilgrastim in pediatric and young adult patients with sarcoma. Patients with sarcoma receiving chemotherapy age 0 to 21 years were eligible. Patients were randomized to receive subcutaneous pegfilgrastim as a single dose of 100 mcg/kg (n= 37) or subcutaneous filgrastim at a dose 5 mcg/kg/day (n=6) following myelosuppressive chemotherapy. Recovery of neutrophil counts was similar in the pegfilgrastim and filgrastim groups. The most common adverse reaction reported was bone pain.

14.2 Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

Efficacy studies of pegfilgrastim products could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Approval of this indication was based on efficacy studies conducted in animals and data supporting pegfilgrastim's effect on severe neutropenia in patients with cancer receiving myelosuppressive chemotherapy *[see Dosage and Administration (2.1)]*.

The recommended dose of UDENYCA is two doses, 6 mg each, administered one week apart for humans exposed to myelosuppressive doses of radiation. For pediatric patients weighing less than 45 kg, dosing of UDENYCA is weight based and is provided in Table 1 *[see Dosage and Administration (2.3)]*. This dosing regimen is based on population modeling and simulation analyses. The exposure associated with this dosing regimen is expected to provide sufficient pharmacodynamic activity to treat humans exposed to myelosuppressive doses of radiation *[see Clinical Pharmacology (12.3)]*. The safety of pegfilgrastim at a dose of 6 mg has been assessed on the basis of clinical experience in patients with cancer receiving myelosuppressive chemotherapy.

The efficacy of pegfilgrastim for the acute radiation syndrome setting was studied in a randomized, placebo-controlled non-human primate model of radiation injury. Rhesus macaques were randomized to either a control (n = 23) or treated (n = 23) cohort. On study day 0, animals (n = 6 to 8 per irradiation day) were exposed to total body irradiation (TBI) of 7.50 ± 0.15 Gy delivered at 0.8 ± 0.03 Gy/min, representing a dose that would be lethal in 50% of animals by 60 days of follow-up (LD50/60). Animals were administered subcutaneous injections of a blinded treatment (control article [5% dextrose in water] or pegfilgrastim [300-319 mcg/kg/day]) on study day 1 and on study day 8. The primary endpoint was survival. Animals received medical management consisting of intravenous fluids, antibiotics, blood transfusions, and other support as required.

Pegfilgrastim significantly (at 0.0014 level of significance) increased 60-day survival in irradiated non-human primates: 91% survival (21/23) in the pegfilgrastim group compared to 48% survival (11/23) in the control group.

16 HOW SUPPLIED/STORAGE AND HANDLING

UDENYCA single-dose prefilled syringe for manual use

UDENYCA (pegfilgrastim-cbqv) injection is a clear, colorless, preservative-free solution supplied in a prefilled single-dose syringe containing 6 mg pegfilgrastim-cbqv, supplied with a 29-gauge, ½-inch needle with an UltraSafe Passive™ Needle Guard.

The needle cap of the prefilled syringe is not made with natural rubber latex.

UDENYCA is provided in a dispensing pack containing one sterile 6 mg/0.6 mL prefilled syringe (NDC 69448-025-63).

UDENYCA prefilled syringe does not bear graduation marks and is intended only to deliver the entire contents of the syringe (6 mg/0.6 mL) for direct administration. Use of the prefilled syringe is not recommended for direct administration for pediatric patients weighing less than 45 kg who require doses that are less than the full contents of the syringe.

Store refrigerated between 2° to 8°C (36° to 46°F) in the carton to protect from light. Do not shake. Discard UDENYCA stored at room temperature for more than 48 hours. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard UDENYCA if frozen more than once.

UDENYCA single-dose prefilled autoinjector

UDENYCA (pegfilgrastim-cbqv) injection is a clear, colorless, preservative-free solution supplied in a prefilled single-dose autoinjector containing 6 mg pegfilgrastim-cbqv.

The needle cap of the prefilled autoinjector is not made with natural rubber latex.

UDENYCA is provided in a dispensing pack containing one 6 mg/0.6 mL prefilled autoinjector (NDC 69448-026-63).

The UDENYCA prefilled autoinjector is not suitable for use in pediatric patients weighing less than 45 kg. The UDENYCA prefilled autoinjector delivers the entire contents (6 mg in 0.6 mL) in a single injection and is not adjustable.

Store refrigerated between 2° to 8°C (36° to 46°F) in the carton to protect from light. Do not shake. Discard UDENYCA stored at room temperature for more than 48 hours. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard UDENYCA if frozen more than once.

UDENYCA ONBODY

UDENYCA ONBODY is provided in a carton containing one sterile prefilled syringe and one sterile on-body injector (OBI) for UDENYCA (NDC 69448-027-63).

The UDENYCA injection single-dose prefilled syringe contains 0.67 mL of a clear, colorless solution that delivers 6 mg/0.6 mL of pegfilgrastim-cbqv when used with the OBI for UDENYCA. The prefilled syringe is supplied with a 29-gauge, 1/2-inch needle. The syringe does not bear graduation marks and is only to be used with the OBI for UDENYCA.

The needle cap of the prefilled syringe is not made with natural rubber latex.

Store UDENYCA ONBODY in the refrigerator at 2°C to 8°C (36°F to 46°F) until 30 minutes prior to use. Because the OBI for UDENYCA is at room temperature during the period of use, UDENYCA ONBODY should not be held at room temperature longer than 12 hours prior to use. Discard UDENYCA ONBODY if stored at room temperature for more than 12 hours.

Do not use the OBI for UDENYCA if its packaging has been previously opened.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Advise patients of the following risks and potential risks with UDENYCA:

- Splenic rupture and splenomegaly
- Acute Respiratory Distress Syndrome
- Serious allergic reactions
- Sickle cell crisis
- Glomerulonephritis
- Increased risk of Myelodysplastic Syndrome and/or Acute Myeloid Leukemia in patients with breast and lung cancer who receive UDENYCA in conjunction with chemotherapy and/or radiation therapy
- Capillary Leak Syndrome
- Aortitis

Advise patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) that efficacy studies of pegfilgrastim products for this indication could not be conducted in humans for ethical and feasibility reasons and that, therefore, approval of this use was based on efficacy studies conducted in animals *[see Clinical Studies (14.2)]*.

Instruct patients who self-administer UDENYCA using the single-dose prefilled syringe of the:

- Importance of following the Instructions for Use (see Instructions for Use).
- Dangers of reusing syringes.
- Importance of following local requirements for proper disposal of used syringes.

For patients who will use the UDENYCA prefilled autoinjector, tell them that they:

- Will hear two "clicks" during the UDENYCA injection. The first ‘click’ means the start of injection and second ‘click’ means the end of injection.
- To start injection, push the prefilled autoinjector body down. Continue holding down after hearing the first ‘click’.
- In the viewing window, the orange indicator will advance to show the progress of the injection.

When injection has finished, there will be a second ‘click’ and the ‘Orange Indicator’ will completely block the viewing window.

Advise patients on the use of the on-body injector (OBI) for UDENYCA:

- Review the Patient Information and Patient Instructions for Use with the patient and provide the instructions to the patient.
- Refer the patient to the dose delivery information written on the Patient Instructions for Use.
- Tell the patient when their dose delivery of UDENYCA will begin and when their dose delivery should be completed.
- Advise the patient that serious allergic reactions can happen with UDENYCA. Patients should have a caregiver nearby for the first use. Patients should plan to be in a place where they can appropriately monitor the OBI for UDENYCA during the approximately 5 minutes UDENYCA delivery and for an hour after the delivery. Advise the patient to avoid traveling, driving, or operating heavy machinery during hours 26-29 following application of the OBI for UDENYCA.
- If the OBI for UDENYCA is placed on the back of the arm, remind the patient that a caregiver must be available to monitor the OBI for UDENYCA.
- If a patient calls the healthcare provider regarding any OBI for UDENYCA problems, the healthcare provider is advised to call Accord BioPharma at 1-866-941-7875.
- Advise the patient:
    - to call their healthcare provider immediately if the status light on the OBI for UDENYCA is flashing red (*see the Patient Instructions for Use*).
    - to inform their healthcare provider if the adhesive on the OBI for UDENYCA becomes saturated with fluid, or there is dripping, as this may be evidence of significant product leakage, resulting in inadequate or missed dose (*see the Patient Instructions for Use*).
    - to keep the OBI for UDENYCA dry for approximately the last 3 hours prior to the dose delivery start to better enable potential leak detection.
    - that the OBI for UDENYCA should only be exposed to temperatures between 41°F and 104°F (5°C to 40°C).
    - to keep the OBI for UDENYCA at least 4 inches away from electrical equipment such as cell phones, cordless telephones, microwaves, and other common appliances. Failure to keep the OBI for UDENYCA at least this recommended distance may interfere with operation and can lead to a missed or incomplete dose of UDENYCA.
    - that if the needle is exposed after OBI for UDENYCA removal, place the used OBI for UDENYCA in a sharps disposal container to avoid accidental needle stick and call their healthcare provider immediately.
    - to remove the OBI for UDENYCA after the green light shines continuously and to place the used OBI for UDENYCA in a sharps disposal container (*see the Patient Instructions for Use*).
- Advise the patient:
    - do not reapply the OBI for UDENYCA if the OBI for UDENYCA comes off before full dose is delivered and instead call their healthcare provider immediately, as they may need a replacement dose.
    - avoid bumping the OBI for UDENYCA or knocking the OBI for UDENYCA off the body.
    - do not use other materials to hold the on-body injector in place that could cover audio/visual indicators or compress the on-body injector against the patient’s skin, as this could dislodge the cannula and lead to a missed dose or incomplete dose of UDENYCA.
    - do not expose the OBI for UDENYCA to medical imaging studies (e.g., X-ray scan, MRI, CT scan and ultrasound), radiation treatment, and oxygen rich environments such as hyperbaric chambers to avoid OBI for UDENYCA damage and patient injury.

- Advise the patient to avoid:
    - airport X-ray scans and request a manual pat down instead; remind patients who elect to request a manual pat down to exercise care to avoid having the OBI for UDENYCA dislodged during the pat down process.
    - sleeping on the OBI for UDENYCA or applying pressure on the OBI for UDENYCA as this may affect OBI for UDENYCA performance.
    - getting body lotions, creams, oils, and cleaning agents near the OBI for UDENYCA as these products may loosen the adhesive.
    - use of lotions, creams, or oils on their arms and abdomen prior to their next scheduled OBI for UDENYCA dose (to help with device adherence to the skin).
    - using bath tubs, hot tubs, whirlpools, or saunas and avoid exposing the OBI for UDENYCA to direct sunlight as these may affect the drug.
    - peeling off or disturbing the OBI for UDENYCA adhesive before delivery of full dose is complete.



UDENYCA® (pegfilgrastim-cbqv)
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