

# PREPARING FOR DECNUPAZ ADMINISTRATION



**A checklist of critical steps to help ensure readiness to appropriately administer DECNUPAZ to your adult patients with BPD CN**

## Pre-treatment coordination

### AWARENESS, TRAINING, AND ACCESS READINESS

- Contact your DECNUPAZ representative to schedule an in-service safety and dosing training
- Confirm appropriate clinical staff have completed DECNUPAZ training
- Contact a DECNUPAZ Field Reimbursement Manager for help navigating access for your patients

## Preparation

### OPERATIONAL READINESS AND LOGISTICS

Before administering DECNUPAZ, ensure you have the appropriate number of vials based on the patient's **actual body weight** and have all preparation/administration components. See the Dosing & Administration Guide and full USPI for more information

## Day before and day of treatment

### ADMINISTRATION READINESS

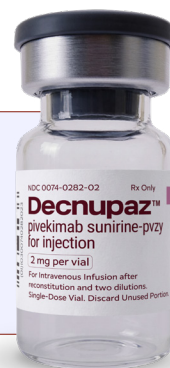
- Confirm product receipt and appropriate storage
- Administer recommended premedications on the day prior to and the day of each DECNUPAZ infusion to reduce the risk of infusion-related reactions
  - On the day of infusion, confirm the patient has adhered to the premedication schedule and is not allergic to sodium metabisulfite
- Review the dosing protocol and post-infusion monitoring plan with the pharmacist and care team

### Need additional support?

Your DECNUPAZ representative is available to assist with training, ordering, and patient support coordination, and can provide additional copies of this checklist.



Scan the QR code or visit [DECNUPAZHCP.com](https://www.rxabbvie.com/decnupaz_hcp) to connect with a DECNUPAZ representative



## INDICATION<sup>1</sup>

DECNUPAZ™ (pivekimab sunirine-pvzy) is indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPD CN).

## IMPORTANT SAFETY INFORMATION<sup>1</sup>

**BOXED WARNING: HEPATOTOXICITY, INCLUDING HEPATIC VENO-OCCLUSIVE DISEASE (VOD) (ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME)**

- DECNUPAZ can cause hepatotoxicity, including severe or fatal hepatic VOD (also known as sinusoidal obstruction syndrome).
- Closely monitor patients for signs and symptoms of VOD, including elevations in liver tests, hepatomegaly (which may be painful), rapid weight gain, and ascites.
- Monitor liver tests, including ALT, AST, and total bilirubin, prior to each dose of DECNUPAZ.
- Delay DECNUPAZ dosage for liver test elevation. Permanently discontinue DECNUPAZ for patients who experience VOD.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information, including BOXED WARNING, or visit [https://www.rxabbvie.com/pdf/decnupaz\\_pi.pdf](https://www.rxabbvie.com/pdf/decnupaz_pi.pdf).

## IMPORTANT SAFETY INFORMATION<sup>1</sup> (continued)

### WARNINGS AND PRECAUTIONS

#### Hepatotoxicity, Including Hepatic VOD

- DECNUPAZ can cause hepatotoxicity, including VOD, a severe form of hepatotoxicity. In CADENZA, VOD occurred in 6% (7/116) of adult patients during treatment or following a subsequent hematopoietic stem cell transplantation (HSCT). Of the 7 total patients that developed VOD, 3 patients had treatment-naïve BPDCN and 4 patients had relapsed/refractory BPDCN. Among all 116 patients treated with DECNUPAZ at 0.045 mg/kg, VOD occurred in 2/116 (2%) during treatment, with onset up to 30 days after the last dose. Among 19 patients with BPDCN who proceeded to HSCT, VOD occurred in 5/19 patients (26%), including 2 fatal cases. The median time from subsequent HSCT to onset of VOD was 11 days (range: 7-25 days).
- After receiving DECNUPAZ, patients should be closely monitored for signs and symptoms of VOD, including elevations in ALT, AST, and total bilirubin; hepatomegaly (which may be painful); rapid weight gain; and ascites. Monitor liver tests, including ALT, AST, and total bilirubin, prior to each dose of DECNUPAZ. Based on elevations of liver tests, delay DECNUPAZ. In patients who experience VOD, discontinue DECNUPAZ and treat according to standard medical practice.

#### Infusion-Related Reactions

- DECNUPAZ can cause serious, life-threatening infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting. In CADENZA, IRR occurred in 26% (30/116) of patients during treatment with DECNUPAZ at 0.045 mg/kg once every 3 weeks, including Grade 1 in 4.3% (5/116), Grade 2 in 16% (19/116), and Grade 3 in 5% (6/116) of patients. IRR occurred in Cycle 1 in 25% (29/116) of patients with decreasing frequency in subsequent cycles. IRR led to discontinuation in 1 patient.
- Premedicate with a corticosteroid the day before infusion, and premedicate with a corticosteroid, antihistamine, and antipyretic prior to dosing. Premedication the day before infusion and prior to dosing led to reduced frequency and severity of IRR.
- Monitor patients closely for potential IRR during the infusion and for at least 4 hours, or longer as clinically indicated, after the first infusion and for at least 1 hour after subsequent infusions.
- Interrupt infusion of DECNUPAZ and institute appropriate medical management if an infusion-related reaction occurs. Depending on the severity of the infusion-related reaction, reduce infusion rate or permanently discontinue.

#### Edema

- DECNUPAZ can cause edema and fluid retention, including serious events. In CADENZA, Grade 3-4 edema occurred in 16% (18/116) of patients treated with DECNUPAZ, including Grade 3-4 generalized edema in 2.6% (3/116) of patients.
- Monitor patients for new or worsening edema. For Grade 2 or 3 edema, delay further dosing of DECNUPAZ until edema has returned to Grades 0-1 or baseline. For Grade 3 edema or Grade 2 edema with dose delay for more than 2 weeks, consider resuming at a lower dose. For Grade 4 edema, permanently discontinue. Institute appropriate medical management for edema.

REFERENCE: 1. DECNUPAZ [package insert]. North Chicago, IL: AbbVie Inc.

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#### Sulfite Allergic Reactions

- DECNUPAZ contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

#### Embryo-Fetal Toxicity

- Based on its mechanism of action, DECNUPAZ can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (FGN849) and affects actively dividing cells.
- Advise patients of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with DECNUPAZ and for 7 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with DECNUPAZ, and for 4 months after the last dose.

#### ADVERSE REACTIONS

- Serious adverse reactions occurred in 55% of patients treated with DECNUPAZ. The most common ( $\geq 2\%$ ) serious adverse reactions were febrile neutropenia, pneumonia, edema, sepsis, hemorrhage, thrombosis, infusion-related reactions, viral infection, pneumonitis, infections without pathogens identified, pyrexia, and musculoskeletal pain. Fatal adverse reactions occurred in 4.3% of patients who received DECNUPAZ, including cardiac arrest (0.9%), clostridium difficile infection (0.9%), failure to thrive (0.9%), depressed level of consciousness (0.9%), and respiratory failure (0.9%).
- The most common adverse reactions ( $\geq 20\%$ ) were edema, fatigue, musculoskeletal pain, hemorrhage, infusion-related reactions, nausea, and diarrhea.
- The most common Grade 3 or 4 laboratory abnormalities ( $\geq 10\%$ ) were decreased neutrophils, decreased platelets, decreased lymphocyte count, decreased white blood cell count, decreased hemoglobin, and increased glucose.

#### DRUG INTERACTIONS

- FGN849 is a substrate of CYP3A. Closely monitor patients for adverse reactions with DECNUPAZ when used concomitantly with strong and moderate CYP3A inhibitors.

#### USE IN SPECIAL POPULATIONS

- **Lactation:** Advise women not to breastfeed during treatment with DECNUPAZ and for 1 month after the last dose.
- **Renal Impairment:** Avoid use of DECNUPAZ in patients with moderate to severe renal impairment (CL<sub>CR</sub> <60 mL/min, estimated by Cockcroft-Gault) or patients with end-stage renal disease.
- **Hepatic Impairment:** Avoid use of DECNUPAZ in patients with moderate to severe hepatic impairment (total bilirubin >1.5 x ULN with any AST).

Please see additional Important Safety Information, including **BOXED WARNING**, throughout.

Please see accompanying full Prescribing Information or visit [https://www.rxabbvie.com/pdf/decnupaz\\_pi.pdf](https://www.rxabbvie.com/pdf/decnupaz_pi.pdf).

