

ADVERSE REACTION MANAGEMENT GUIDE

This guide provides DECNUPAZ PI-based direction for managing adverse reactions

INDICATION¹

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

IMPORTANT SAFETY INFORMATION¹

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 full [Important Safety Information](#), including **BOXED WARNING**, on pages 10–12. Please see full [Prescribing Information](#).

CADENZA overview

CADENZA study design^{1,2}

- CADENZA was a multicenter, open-label, single-arm Phase 1/2 clinical trial evaluating DECNUPAZ 0.045 mg/kg IV once every 3 weeks in adults with treatment-naïve* BPDCN with no CNS involvement or relapsed/refractory BPDCN without evidence of active CNS disease
- 116 adult patients with newly diagnosed or relapsed/refractory myeloid malignancies, including 84 with BPDCN
- Median number of cycles administered:
 - In all patients (N=116) with newly diagnosed or relapsed/refractory myeloid malignancies: 3 cycles (range: 1–34)
 - Patients with BPDCN (n=84): 3.5 cycles (range: 1–34)

Serious and common adverse reactions¹

- **Serious adverse reactions** occurred in 55% of patients treated with DECNUPAZ. **The most common (≥2%) serious adverse reactions** were febrile neutropenia, pneumonia, edema, sepsis, hemorrhage, thrombosis, infusion-related reactions, viral infection, pneumonitis, infections without specified pathogens, 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 (≥20%) adverse reactions** were edema, fatigue, musculoskeletal pain, hemorrhage, infusion-related reactions, nausea, and diarrhea
- **The most common Grade 3 to 4 laboratory abnormalities (≥10%)** were decreased neutrophils, decreased platelets, decreased lymphocyte count, decreased white blood cells, decreased hemoglobin, and increased glucose

Discontinuations and dose reductions due to adverse reactions¹

- Permanent discontinuation due to adverse reactions occurred in 10% of patients who received DECNUPAZ. Adverse reactions which resulted in permanent discontinuation of DECNUPAZ in ≥1% of patients included veno-occlusive disease and pneumonitis
- Adverse reactions led to:
 - Dose reductions in 6% of patients
 - Adverse reactions which required dose reductions in ≥2% of patients included edema
 - Dose interruptions in 37% of patients
 - Adverse reactions which resulted in dose interruptions in ≥2% of patients included edema, pneumonia, infusion-related reaction, bacterial infections, fatigue, hemorrhage, neutropenia, pneumonitis, and pyrexia

*Included patients with de novo BPDCN (n=22) and patients with prior or concomitant hematologic malignancy (PCHM; n=11), with no CNS involvement.¹

Adverse reactions

Adverse Reactions (≥10%) in Patients Who Received DECNUPAZ in CADENZA¹

ADVERSE REACTION ^a	DECNUPAZ (N=116)	
	ALL GRADES (%)	GRADE 3 OR 4 (%)
General disorders and administration site conditions		
Edema ^b	52	16
Fatigue ^c	34	5
Pyrexia ^c	16	0.9
Chills	11	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain ^c	34	8
Vascular disorders		
Hemorrhage ^c	28	6
Thrombosis ^c	13	5
Injury, poisoning, and procedural complications		
Infusion-related reactions	26	5
Fall	13	1.7
Gastrointestinal disorders		
Nausea ^c	24	0.9
Diarrhea ^c	21	0.9
Constipation	19	0
Abdominal pain ^c	14	0.9
Respiratory, thoracic, and mediastinal disorders		
Dyspnea ^c	19	1.7
Cough ^c	15	0
Skin and subcutaneous tissue disorders		
Rash ^d	19	0
Nervous system disorders		
Neuropathy peripheral ^e	18	1.7
Headache ^c	16	2.6
Dizziness ^c	10	0.9
Metabolism and nutrition disorders		
Decreased appetite ^c	16	0.9
Infections and infestations		
Infections without specified pathogens ^c	16	6
Viral infections ^f	13	6
Bacterial infections ^g	12	5
Pneumonia ^h	11	9
Psychiatric disorders		
Insomnia	15	0
Blood and lymphatic system disorders		
Febrile neutropenia	11	11

The median number of cycles administered was 3 (range: 1 to 34) in the overall population, and 3.5 (range: 1 to 34) in patients with BPDCN.¹

^aAdverse reactions were graded based on CTCAE Version 4.03.¹

^bEdema includes acute pulmonary edema, face edema, generalized edema, hypervolemia, edema, edema genital, edema peripheral, pericardial effusion, peripheral swelling, pleural effusion, pulmonary edema, swelling face, weight increase, ascites.¹

^cConsists of multiple related terms.¹

^dRash includes erythema, erythema nodosum, guttate psoriasis, photosensitivity reaction, psoriasis, rash, rash erythematous, rash macular, rash maculo-papular, rash pruritic, skin lesion, skin lesion inflammation, stasis dermatitis.¹

^eNeuropathy peripheral includes burning sensation, dysesthesia, facial nerve disorder, hypoesthesia, IIIrd nerve disorder, neuralgia, neuropathy peripheral, paresthesia, sciatica.¹

^fViral infections include COVID-19, cytomegalovirus infection, HCoV-229E infection, herpes simplex, herpes zoster, herpes zoster disseminated, influenza, ophthalmic herpes simplex, oral herpes.¹

^gBacterial infections include cellulitis, *Clostridium difficile* infection, erysipelas, folliculitis, vulval abscess.¹

^hPneumonia includes *Pneumocystis jirovecii* pneumonia, pneumonia, pneumonia viral.¹

 **Decnupaz™**
pivekimab sunirine-pvzy
injection for intravenous use 2 mg

Please see full [Important Safety Information](#), including **BOXED WARNING**, on pages 10–12. Please see full [Prescribing Information](#).

Treatment modifications

Recommended Dosage Modifications for Adverse Reactions ¹		
ADVERSE REACTION	SEVERITY ^a	DOSE MODIFICATION GUIDELINES
Veno-occlusive disease	Any Grade	<ul style="list-style-type: none"> Permanently discontinue DECNUPAZ
Increased AST or ALT	Either AST or ALT is $>2.5 \times$ the ULN	<ul style="list-style-type: none"> Delay further DECNUPAZ dosing until AST or ALT have returned to $\leq 2.5 \times$ the ULN
Increased bilirubin	Total bilirubin $>1.5 \times$ the ULN	<ul style="list-style-type: none"> Delay further DECNUPAZ dosing until total bilirubin has returned to $\leq 1.5 \times$ the ULN
Infusion-related reactions	Grade 2	<ul style="list-style-type: none"> Interrupt DECNUPAZ infusion and institute appropriate medical management After full resolution of symptoms, resume DECNUPAZ infusion at 50% of the previous rate and if no further symptoms appear, increase rate as appropriate until infusion is completed
	Grade 3	<ul style="list-style-type: none"> Stop DECNUPAZ infusion and institute appropriate medical management After full resolution of symptoms, resume the infusion at 50% of the previous rate If symptoms recur, permanently discontinue
	Grade 4	<ul style="list-style-type: none"> Permanently discontinue DECNUPAZ
Edema	Grade 1 (5-10% inter-limb discrepancy in volume or circumference, 4 kg weight gain, or 1+ pitting edema [2 mm])	<ul style="list-style-type: none"> Follow weekly weights Consider administering diuretic therapy
	Grade 2 (10-30% inter-limb discrepancy in volume or circumference, >4 kg weight gain, or 2+ pitting edema [4 mm])	<ul style="list-style-type: none"> Administer diuretic therapy Manage hypoalbuminemia as needed Delay further DECNUPAZ dosing until edema has returned to Grade 0-1 or baseline If delayed more than 2 weeks, consider dose reduction before resuming
	Grade 3 ($>30\%$ inter-limb discrepancy in volume, or 3+/4+ pitting edema [>6 mm])	<ul style="list-style-type: none"> Consider combination diuretic therapy Manage hypoalbuminemia as needed Delay further DECNUPAZ dosing until edema has returned to Grade 0-1 or baseline Consider resuming DECNUPAZ infusion at 0.015 mg/kg IV once every 3 weeks
	Grade 4 (life-threatening)	<ul style="list-style-type: none"> Permanently discontinue DECNUPAZ
Other non-hematologic adverse reactions	Grade 3	<ul style="list-style-type: none"> Delay further DECNUPAZ dosing until resolved to \leq Grade 2 or baseline
	Grade 4	<ul style="list-style-type: none"> Permanently discontinue DECNUPAZ

^aNCI CTCAE Version 4.03; Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.¹

ALT=alanine aminotransferase; AST=aspartate aminotransferase

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Hepatotoxicity, including hepatic veno-occlusive disease (also known as sinusoidal obstruction syndrome)

Incidence and discontinuation^{1,2}

- VOD occurred in 6% (7/116) of adult patients during treatment or following a subsequent HSCT
 - 3 patients had treatment-naïve BPDCN and 4 patients had relapsed/refractory BPDCN
- VOD occurred in 2% (n/N=2/116) of patients during treatment with DECNUPAZ, with onset up to 30 days after the last dose
 - Both events resolved but led to treatment discontinuation
- Of the 19 patients with BPDCN who went on to receive HSCT after completing treatment with DECNUPAZ, VOD occurred in 5 of 19 patients. Of those 5 patients with VOD, 2 events were fatal. The median time from subsequent HSCT to onset of VOD was 11 days (range: 7–25 days)



Counsel your patients on signs and symptoms including¹:

- Jaundice
- Rapid weight gain
- Dark urine
- Abdominal pain or distention

Management Considerations for VOD¹

SEVERITY OF ADVERSE REACTION ^a	ANY GRADE
Dose modification	<ul style="list-style-type: none"> • Permanently discontinue DECNUPAZ
Monitoring & management	<ul style="list-style-type: none"> • 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

CADENZA protocol qualitative scale grading⁴

For adverse reactions not listed in CTCAE v4.03:

- **Grade 1:** No limitation of usual activities
- **Grade 2:** Some limitation of usual activities
- **Grade 3:** Inability to carry out usual activities
- **Grade 4:** Immediate risk of death
- **Grade 5:** Resulting in death

^aNCI CTCAE Version 4.03; Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.¹

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Increased AST/ALT and bilirubin

Management Considerations for Increased AST or ALT¹

SEVERITY OF ADVERSE REACTION ^a	EITHER AST OR ALT >2.5 × ULN
Dose modification	<ul style="list-style-type: none">• Delay further DECNUPAZ dosing until AST or ALT have returned to $\leq 2.5 \times$ the ULN
Monitoring & management	<ul style="list-style-type: none">• Monitor liver tests, including ALT and AST, prior to each dose of DECNUPAZ. Based on elevations of liver tests, delay DECNUPAZ

NCI CTCAE v4.03 grading: AST increased and ALT increased³

- Grade 1: >ULN–3.0 × ULN
- Grade 2: >3.0–5.0 × ULN
- Grade 3: >5.0–20.0 × ULN
- Grade 4: >20.0 × ULN

Management Considerations for Increased Bilirubin¹

SEVERITY OF ADVERSE REACTION ^a	TOTAL BILIRUBIN >1.5 × ULN
Dose modification	<ul style="list-style-type: none">• Delay further DECNUPAZ dosing until total bilirubin has returned to $\leq 1.5 \times$ ULN
Monitoring & management	<ul style="list-style-type: none">• Monitor liver tests, including total bilirubin, prior to each dose of DECNUPAZ. Based on elevations of liver tests, delay DECNUPAZ

NCI CTCAE v4.03 grading: Bilirubin increased³

- Grade 1: >ULN–1.5 × ULN
- Grade 2: >1.5–3.0 × ULN
- Grade 3: >3.0–10.0 × ULN
- Grade 4: >10.0 × ULN

^aNCI CTCAE Version 4.03; Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.¹

ALT=alanine aminotransferase; AST=aspartate aminotransferase

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Infusion-related reactions

Incidence and discontinuation¹

- Occurred in 26% (n/N=30/116) of patients during treatment with DECNUPAZ. Included Grade 1 in 4.3% (n/N=5/116), Grade 2 in 16% (n/N=19/116), and Grade 3 in 5% (n/N=6/116) of patients
- Infusion-related reactions occurred in Cycle 1 in 25% (n/N=29/116) of patients, with decreasing frequency in subsequent cycles
- One patient discontinued treatment due to infusion-related reactions



Counsel your patients on signs and symptoms including¹:

- Chills
- Tachycardia
- Hypotension
- Fever
- Tachypnea
- Dyspnea

Management Considerations for Infusion-Related Reactions¹

SEVERITY OF ADVERSE REACTION ^a	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Dose modification	<ul style="list-style-type: none"> • Maintain infusion rate 	<ul style="list-style-type: none"> • Interrupt DECNUPAZ infusion and institute appropriate medical management • After full resolution of symptoms, resume DECNUPAZ infusion at 50% of the previous rate and if no further symptoms appear, increase rate as appropriate until infusion is completed 	<ul style="list-style-type: none"> • Stop DECNUPAZ infusion and institute appropriate medical management • After full resolution of symptoms, resume the infusion at 50% of the previous rate • If symptoms recur, permanently discontinue 	<ul style="list-style-type: none"> • Permanently discontinue DECNUPAZ
Premedication	<ul style="list-style-type: none"> • Administer a prophylactic corticosteroid the day before infusion. Administer a corticosteroid, an antihistamine, and an antipyretic 30-60 minutes prior to infusion 			
Monitoring & management	<ul style="list-style-type: none"> • Monitor patients closely for potential infusion-related reactions 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 			

NCI CTCAE v4.03 grading: Infusion-related reactions³

- **Grade 1:** Mild transient reaction; infusion interruption not indicated; intervention not indicated
- **Grade 2:** Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤24 hrs
- **Grade 3:** Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae
- **Grade 4:** Life-threatening consequences; urgent intervention indicated
- **Grade 5:** Death

^aNCI CTCAE Version 4.03; Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.¹



Edema*

Incidence and discontinuation^{1,2,5,6}

- Grade 3–4 edema occurred in 16% (n/N=18/116) of patients during treatment with DECNUPAZ, including Grade 3–4 generalized edema (2.6%; n/N=3/116)
- Events were mostly mild to moderate
 - Grade 3–4: 16% (n/N=18/116)
 - All Grades: 52% (n/N=60/116)
- 45% (n/N=52/116) of patients in CADENZA experienced peripheral edema
- Peripheral edema in all patients in CADENZA per cycle (N=116)
 - Cycle 1: n/N=12/116 (10%); Cycle 2: n/N=12/97 (12%); Cycle 3: n/N=19/74 (26%); Cycle 4: n/N=14/51 (28%); Cycle 5: n/N=7/41 (17%)



Counsel your patients on signs and symptoms including¹:

- Swelling
- Weight gain
- Shortness of breath
- Fluid retention or difficulty breathing

Management Considerations for Edema¹

SEVERITY OF ADVERSE REACTION ^a	GRADE 1 (5-10% inter-limb discrepancy in volume or circumference, 4 kg weight gain, or 1+ pitting edema [2 mm])	GRADE 2 (10-30% inter-limb discrepancy in volume or circumference, >4 kg weight gain, or 2+ pitting edema [4 mm])	GRADE 3 (>30% inter-limb discrepancy in volume, or 3+/4+ pitting edema [>6 mm])	GRADE 4 (life threatening)
Dose modification	<ul style="list-style-type: none"> • Follow weekly weights • Consider administering diuretic therapy 	<ul style="list-style-type: none"> • Administer diuretic therapy • Manage hypoalbuminemia as needed • Delay further DECNUPAZ dosing until edema has returned to Grade 0–1 or baseline • If delayed more than 2 weeks, consider dose reduction before resuming 	<ul style="list-style-type: none"> • Consider combination diuretic therapy • Manage hypoalbuminemia as needed • Delay further DECNUPAZ dosing until edema has returned to Grade 0–1 or baseline • Consider resuming DECNUPAZ infusion at 0.015 mg/kg IV once every 3 weeks 	<ul style="list-style-type: none"> • Permanently discontinue DECNUPAZ
Monitoring & management	<ul style="list-style-type: none"> • DECNUPAZ can cause edema and fluid retention, including serious events • Monitor patients for new or worsening edema • For Grade 2 or 3 edema, delay further dosing until edema has returned to Grade 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 			

*Edema includes acute pulmonary edema, face edema, generalized edema, hypervolemia, edema, edema genital, edema peripheral, pericardial effusion, peripheral swelling, pleural effusion, pulmonary edema, swelling face, weight increase, ascites.¹

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Other non-hematologic adverse reactions

Management Considerations for Other Non-hematologic Adverse Reactions ¹		
SEVERITY OF ADVERSE REACTION ^a	GRADE 3	GRADE 4
Dose modification	Delay further DECNUPAZ dosing until resolved to \leq Grade 2 or baseline	Permanently discontinue DECNUPAZ

CADENZA protocol qualitative scale grading⁴

For adverse reactions not listed in CTCAE v4.03:

- **Grade 1:** No limitation of usual activities
- **Grade 2:** Some limitation of usual activities
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INDICATION AND IMPORTANT SAFETY INFORMATION¹

INDICATION¹

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

IMPORTANT SAFETY INFORMATION¹

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- 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.

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.

INDICATION AND IMPORTANT SAFETY INFORMATION (Cont'd)¹

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.

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.

INDICATION AND IMPORTANT SAFETY INFORMATION (Cont'd)¹

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 (CLcr < 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 $> 1.5 \times$ ULN with any AST).

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



DECNUPAZ is a treatment option with
**defined steps to help navigate and
manage safety considerations**

For comprehensive resources to support your practice,
visit [DECNUPAZHCP.com](https://www.decnupazhcp.com)

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- 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.

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ALT=alanine aminotransferase; AST=aspartate aminotransferase; BPDCN=blastic plasmacytoid dendritic cell neoplasm; CNS=central nervous system; COVID-19=Coronavirus Disease of 2019; CTCAE=Common Terminology Criteria for Adverse Events; HCoV-229E=Human Coronavirus-229E; HSCT=hematopoietic stem cell transplantation; IV=intravenous; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; NSAID=nonsteroidal anti-inflammatory drug; ULN=upper limit of normal; VOD=veno-occlusive disease

REFERENCES: **1.** DECNUPAZ [package insert]. North Chicago, IL: AbbVie Inc. **2.** Pemmaraju N, Marconi G, Montesinos P, et al. Pivekimab sunirine in blastic plasmacytoid dendritic cell neoplasm. *J Clin Oncol.* 2026;00;1-13. **3.** National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) v4.03. Published June 14, 2010. Accessed November 10, 2025. https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf **4.** Pemmaraju N, Marconi G, Montesinos P, et al. Protocol to: Pivekimab sunirine in blastic plasmacytoid dendritic cell neoplasm. *J Clin Oncol.* 2026;00;1-13. **5.** Data on file, AbbVie Inc. ABVRR183362. **6.** Data on file, AbbVie Inc. ABVRR183313.

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