# PRODUCT INFORMATION & DISTRIBUTION GUIDE

ZYNYZ®
retifanlimab-dlwr
Injection 500 mg

| | |
|---|---|
| **Manufactured By** | Incyte Corporation - **1-855-463-3463** |
| **Marketed By** | Incyte Corporation - **www.Incyte.com** |
| **Product Name** | ZYNYZ® |
| **Generic Name** | retifanlimab-dlwr |
| **Product Website** | **www.ZYNYZHCP.com** |


## NATIONAL DRUG CODE (NDC)

| 500 mg/20 mL (25 mg/mL) | 10-Digit | 11-Digit |
|---|---|---|
| | 50881-006-03 | 50881-**0**006-03 |

## HCPCS CODING

**J9345** (Injection, retifanlimab-dlwr, 1 mg)
Effective October 1, 2023

## WHOLESALE ACQUISITION COST (WAC)

**$15,038/vial**
WAC current as of January 2026

HCPCS, Healthcare Common Procedure Coding System.

## PRODUCT BARCODES

Use the barcodes shown here to facilitate the loading of ZYNYZ into your EHR platform.

**Carton**

N 3 50881-00603 6

**Vial**

N 3 5088-1006-03 6

## INDICATIONS AND USAGE

### Squamous Cell Carcinoma of the Anal Canal

ZYNYZ, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC).

ZYNYZ, as a single agent, is indicated for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy.

### Merkel Cell Carcinoma

ZYNYZ is indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).

## IMPORTANT SAFETY INFORMATION

### Severe and Fatal Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed may not be inclusive of all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can occur at any time after starting or discontinuing treatment with a PD-1/PD-L1–blocking antibody, and can affect more than one body system simultaneously.

Monitor patients closely for symptoms and signs that may be clinical manifestations of such reactions. Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1–blocking antibodies. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. If suspected, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

## ORDERING & DISTRIBUTION

ZYNYZ retifanlimab-dlwr Injection 500 mg

**ZYNYZ® is available through the following network of Specialty Distributors:**

CardinalHealth | cencora | McKESSON

**Prescribers who do not wish to use buy-and-bill should check with their preferred Specialty Pharmacy for availability. Specialty Pharmacies may obtain access to ZYNYZ through the Specialty Distributors above.**

## HOW SUPPLIED

| | |
|---|---|
| **Sales Unit** | One single-dose vial: 500 mg/20 mL (25 mg/mL) |
| **Units Per Carton** | One vial per carton |
| **Pack Dimensions (Approximate)** | Length: 2.3622” \| Width: 1.3779” \| Height: 2.9531” |
| **Global Trade Identification Numbers** | 00350881006036 (Sales Unit)<br>30350881006037 (Shipper) |
| **Product Expiration** | Expiration date printed on both single-dose vial and carton |

## DESCRIPTION

500 mg/20 mL (25 mg/mL), sterile, preservative-free, clear to slightly opalescent, colorless to pale yellow solution, free from visible particles in a single-dose vial.

## STORAGE & HANDLING

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake.

## IMPORTANT SAFETY INFORMATION (CONT)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Withhold or permanently discontinue ZYNYZ depending on severity. In general, if ZYNYZ requires interruption or discontinuation, administer systemic corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) until improvement to ≤ Grade 1. Then, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroids.

Immune-Mediated Pneumonitis

ZYNYZ can cause immune-mediated pneumonitis. Immune-mediated pneumonitis occurred in 3.1% (14/452) of patients, including 1 (0.2%) patient with fatal pneumonitis, Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Pneumonitis led to permanent discontinuation of ZYNYZ in 1 patient and withholding in 1.1%.

Systemic corticosteroids were required in 71% (10/14) of patients. Pneumonitis resolved in 11 of the 14 patients.

Immune-Mediated Colitis

ZYNYZ can cause immune-mediated colitis. Cytomegalovirus infections/reactivations have occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

*ZYNYZ as a Single Agent:* Immune-mediated colitis occurred in 2.7% (12/452) of patients, including Grade 4 (0.2%), Grade 3 (0.4%), and Grade 2 (1.1%). Colitis led to permanent discontinuation of ZYNYZ in 0.9% of patients and withholding in 1.3%. Systemic corticosteroids were required in 75% (9/12) of patients. Colitis resolved in 8/12 patients.

# CONTACT INFORMATION

ZYNYZ® retifanlimab-dlwr Injection 500 mg

## PRODUCT INFORMATION

For additional information on ZYNYZ®, please contact:

Phone: 1-855-463-3463

Email: MedInfo@Incyte.com

## US MEDICAL INFORMATION INQUIRIES

For all medical information requests, please contact Incyte Medical Information:

Phone: 1-855-463-3463

Email: MedInfo@Incyte.com

## PRODUCT RETURNS

Credit for returns is subject to Incyte's current Specialty Return Goods Policy. Please request a Return Goods Authorization by calling:

1-855-751-7958

## ADVERSE EVENT REPORTING

Contact Incyte or the FDA to report an adverse event.

**Incyte:**

Phone: 1-855-463-3463

Email: MedInfo@Incyte.com

**FDA:**

Phone: 1-800-FDA-1088

Web: www.fda.gov/medwatch

## IMPORTANT SAFETY INFORMATION (CONT)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Immune-Mediated Colitis (cont)

*ZYNYZ in Combination with Carboplatin and Paclitaxel:* Immune-mediated colitis occurred in 10% (16/154) of patients receiving ZYNYZ in combination with carboplatin and paclitaxel, including Grade 4 (0.6%), Grade 3 (2.6%), and Grade 2 (3.2%). Colitis led to permanent discontinuation of ZYNYZ in 2 patients and withholding of ZYNYZ in 2 patients. Systemic corticosteroids were required in 94% (15/16) of patients. Colitis resolved in 15 of the 16 patients.

Immune-Mediated Hepatitis

ZYNYZ can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 3.5% (16/452) of patients, including Grade 4 (0.2%), Grade 3 (2.4%), and Grade 2 (0.9%). Hepatitis led to permanent discontinuation of ZYNYZ in 1.5% of patients and withholding in 1.1%.

Systemic corticosteroids were required in 81% (13/16) of patients. Hepatitis resolved in 9/16 patients.

Immune-Mediated Endocrinopathies

*Adrenal Insufficiency*

ZYNYZ can cause primary or secondary adrenal insufficiency. For ≥ Grade 2 adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

*ZYNYZ as a Single Agent:* Adrenal insufficiency occurred in 0.9% (4/452) of patients, including Grade 3 (0.4%) and Grade 2 (0.4%). ZYNYZ was permanently discontinued in no patients and was withheld for 1 patient with adrenal insufficiency. All patients required systemic corticosteroids. Adrenal insufficiency resolved in 1 of the 4 patients.

*ZYNYZ in Combination with Carboplatin and Paclitaxel:* Adrenal insufficiency occurred in 5.8% (9/154) of patients receiving ZYNYZ in combination with carboplatin and paclitaxel, including Grade 3 and Grade 2 (1.9% each). Adrenal insufficiency led to permanent discontinuation of ZYNYZ in 1 patient and withholding of ZYNYZ in 3 patients. All patients required systemic corticosteroids. Adrenal insufficiency resolved in 4 of the 9 patients.

*Hypophysitis*

ZYNYZ can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts, and can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

Hypophysitis occurred in 0.7% (3/452) of patients receiving ZYNYZ, including Grade 3 (0.2%) and Grade 2 (0.4%). Hypophysitis led to permanent discontinuation of ZYNYZ in 1 patient and withholding of ZYNYZ in 1 patient.

All patients required systemic steroids. Hypophysitis resolved in 1 of the 3 patients.

*Thyroid Disorders*

ZYNYZ can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

Thyroiditis occurred in 0.7% (3/452, all Grade 1) of patients. No patients discontinued or withheld ZYNYZ due to thyroiditis. Thyroiditis resolved in 1 of the 3 patients.

# DOSAGE & ADMINISTRATION HIGHLIGHTS

ZYNYZ® retifanlimab-dlwr Injection 500 mg

## Recommended Dosage of ZYNYZ® by Indication

| INDICATION | RECOMMENDED DOSAGE OF ZYNYZ | DURATION OF TREATMENT |
|---|---|---|
| **Combination Therapy[a]** | | |
| Adult patients with inoperable locally recurrent or metastatic SCAC | 500 mg every 4 weeks[b] | Until disease progression, unacceptable toxicity, or up to 12 months |
| **Monotherapy** | | |
| Adult patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy | 500 mg every 4 weeks[b] | Until disease progression, unacceptable toxicity, or up to 24 months |
| Adult patients with metastatic or recurrent locally advanced MCC | 500 mg every 4 weeks[b] | Until disease progression, unacceptable toxicity, or up to 24 months |

[a] Refer to the Prescribing Information for the agents administered in combination with ZYNYZ for recommended dosing information, as appropriate.

[b] 30-minute intravenous infusion.

Administer ZYNYZ as an intravenous infusion after dilution.

**Please see the Full Prescribing Information for dosage modifications for adverse reactions.**

## Preparation and Administration

Visually inspect the vial for particulate matter and discoloration prior to administration. ZYNYZ is a clear to slightly opalescent, colorless to pale yellow solution and is free of particles. Discard the vial if the solution is cloudy, discolored, or contains particulate matter.

Do not shake the vial.

**Preparation**

1. Withdraw 20 mL (500 mg) of ZYNYZ from one vial and discard vial with any unused portion.
2. Dilute ZYNYZ with either 0.9% Sodium Chloride Injection, or 5% Dextrose Injection, to a final concentration between 1.4 mg/mL and 10 mg/mL. Use polyvinylchloride (PVC) and di-2-ethylhexyl phthalate (DEHP), polyolefin copolymer, polyolefin with polyamide, or ethylene vinyl acetate infusion bags.
3. Mix diluted solution by gentle inversion. Do not shake.
4. Visually inspect the infusion bag for particulate matter and discoloration prior to administration. Discard if the solution is discolored or contains particulate matter.

**Storage of Diluted ZYNYZ Solution**

Protect the diluted ZYNYZ solution from light during storage.

Store diluted ZYNYZ solution:

- At room temperature [up to 25°C (77°F)] for no more than 8 hours from the time of preparation to the end of the infusion.

  OR
- Under refrigeration at 2°C to 8°C (36°F to 46°F) for no more than 24 hours from the time of preparation to the end of the infusion. If refrigerated, allow the diluted solution to come to room temperature prior to administration. The diluted solution must be administered within 4 hours (including infusion time) once it is removed from the refrigerator.

Do not freeze or shake diluted solution.

**Administration**

- Administer diluted ZYNYZ solution by intravenous infusion over 30 minutes through a polyethylene, polyurethane, or PVC with DEHP intravenous line containing a sterile, non-pyrogenic, low-protein binding polyethersulfone, polyvinylidene fluoride, or cellulose acetate 0.2 micron to 5 micron in-line or add-on filter or 15 micron mesh in-line or add-on filter. Do NOT administer ZYNYZ as an intravenous push or bolus injection.
- Do not co-administer other drugs through the same infusion line.

# PATIENT SUPPORT PROGRAM

ZYNYZ® retifanlimab-dlwr Injection 500 mg

**IncyteCARES for ZYNYZ® Supports Eligible Patients During Treatment**

The IncyteCARES mission is to help patients start and stay on therapy by assisting with access and as-needed support.

IncyteCARES can help patients understand their health insurance coverage, can provide reimbursement support, and offers savings, financial assistance, and support options for eligible patients,* including:

**IncyteCARES for ZYNYZ Savings Program**
For Eligible Patients With Commercial Health Insurance

**IncyteCARES for ZYNYZ Patient Assistance Program**
For Eligible Patients Who Are Uninsured or Underinsured for ZYNYZ

**Information About Nonprofit or Other Support Organizations**
For All Patients

IncyteCARES

**The IncyteCARES Team Is Available by Phone Every Weekday**
Call **1-855-452-5234**, Monday to Friday 8 AM - 8 PM ET
Visit **HCP.IncyteCARES.com/ZYNYZ** to learn more

*Terms and conditions apply. Program terms may change at any time.

## IMPORTANT SAFETY INFORMATION (CONT)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Immune-Mediated Endocrinopathies (cont)

*Hypothyroidism*

Hypothyroidism occurred in 10% (46/452) of patients receiving ZYNYZ, including Grade 2 (4.9%). No patients discontinued due to hypothyroidism. ZYNYZ was withheld in 0.4% of patients.

Systemic corticosteroids were required for 1 patient, and 78% (36/46) of patients received endocrine therapy.

*Hyperthyroidism*

Hyperthyroidism occurred in 6% (26/452) of patients receiving ZYNYZ, including Grade 2 (2.7%). ZYNYZ was not discontinued in any patient and was withheld in 0.4% of patients. Systemic corticosteroids were required for 15% (4/26) of patients, and 50% (13/26) of patients received endocrine therapy.

*Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis*

Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold ZYNYZ depending on severity.

Type 1 diabetes mellitus occurred in 0.2% (1/452) of patients, including Grade 3 (0.2%).

Immune-Mediated Nephritis with Renal Dysfunction

ZYNYZ can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 2% (9/452) of patients receiving ZYNYZ, including Grade 4 (0.4%), Grade 3 (1.1%), and Grade 2 (0.4%). Nephritis led to permanent discontinuation of ZYNYZ in 1.1% of patients and withholding in 0.7% of patients.

Systemic corticosteroids were required in 67% (6/9) of patients. Nephritis resolved in 4/9 patients.

Immune-Mediated Dermatologic Adverse Reactions

ZYNYZ can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue ZYNYZ depending on severity.

Immune-mediated skin reactions occurred in 10% (43/452) of patients, including Grade 4 (0.2%), Grade 3 (1.1%), and Grade 2 (8%). Immune-mediated dermatologic adverse reactions led to permanent discontinuation of ZYNYZ in 0.7% of patients and withholding in 2.7% of patients.

Systemic corticosteroids were required in 33% (14/43) of patients. Immune-mediated dermatologic adverse reactions resolved in 72% (31/43) of patients.

### Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of < 1% in 452 patients who received ZYNYZ or were reported with the use of other PD-1/PD-L1–blocking antibodies, including severe or fatal cases.

*Cardiac/vascular:* myocarditis, pericarditis, vasculitis

*Gastrointestinal:* pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis

*Musculoskeletal:* myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis, polymyalgia rheumatica

*Neurological:* meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy

*Ocular:* uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

*Endocrine:* hypoparathyroidism

*Other (Hematologic/Immune):* hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

### Infusion-Related Reactions

A severe infusion-related reaction (Grade 3) occurred in 5 (0.8%) of 606 patients receiving ZYNYZ. Monitor patients for signs and symptoms; interrupt or slow the rate of infusion or permanently discontinue ZYNYZ based on severity of reaction. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

### Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause), which may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

### Embryo-Fetal Toxicity

ZYNYZ can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus, resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

### Lactation

Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

### Adverse Reactions

*Metastatic or Recurrent Locally Advanced MCC: ZYNYZ as a Single Agent*

The safety of ZYNYZ was evaluated in 107 patients with metastatic or recurrent locally advanced MCC.

Serious adverse reactions occurred in 26% of patients receiving ZYNYZ. The most frequent serious adverse reactions (≥ 2% of patients) were fatigue, arrhythmia, and pneumonitis.

Permanent discontinuation of ZYNYZ due to an adverse reaction occurred in 21% of patients. These included asthenia, colitis, demyelinating polyneuropathy, diarrhea, drug hypersensitivity, eosinophilic fasciitis, hepatitis, hypophysitis, increased transaminases, infusion-related reaction, pancreatitis, polyarthritis, radiculopathy, toxic epidermal necrolysis, and tubulointerstitial nephritis (1 patient each).

Dosage interruptions due to an adverse reaction occurred in 39% of patients. Adverse reactions or laboratory abnormalities that required dosage interruption in > 2% of patients were increased transaminases, increased lipase, increased amylase, and pyrexia.

The most common (≥ 10%) adverse reactions were musculoskeletal pain, fatigue, pruritus, diarrhea, rash, pyrexia, nausea, and constipation.

## IMPORTANT SAFETY INFORMATION (CONT)

**Adverse Reactions (cont)**

*Inoperable Locally Recurrent or Metastatic SCAC: ZYNYZ in Combination with Carboplatin and Paclitaxel*

The safety of ZYNYZ in patients with inoperable locally recurrent or metastatic SCAC was evaluated in 154 patients enrolled in the POD1UM-303 trial.

Serious adverse reactions occurred in 47% of patients receiving ZYNYZ in combination with carboplatin and paclitaxel. The most frequent serious adverse reactions (≥ 2% of patients) were sepsis (3.2%), pulmonary embolism (3.2%), diarrhea (2.6%), and vomiting (2.6%).

In patients receiving ZYNYZ in combination with carboplatin and paclitaxel, ZYNYZ was permanently discontinued due to an adverse reaction in 11% of patients. Adverse reactions that resulted in permanent discontinuation of ZYNYZ included immune-mediated enterocolitis (2 patients) and warm autoimmune hemolytic anemia, hepatitis, adrenal insufficiency, blood bilirubin increased, AST increased, blood alkaline phosphatase increased, arthritis, encephalopathy, peripheral sensorimotor neuropathy, hypothyroidism, immune-mediated cholangitis, pruritus, malaise, and rash (1 patient each).

Dosage interruptions due to an adverse reaction, excluding temporary interruptions due to infusion-related reactions, occurred in 55% of patients who received ZYNYZ in combination with carboplatin and paclitaxel. Adverse reactions that resulted in dosage interruptions in ≥ 2% of patients were neutropenia, anemia, thrombocytopenia, leukopenia, fatigue, COVID-19, and urinary tract infection.

The most common (≥ 20%) adverse reactions were fatigue, peripheral neuropathy, nausea, alopecia, diarrhea, musculoskeletal pain, constipation, hemorrhage, rash, vomiting, decreased appetite, pruritus, and abdominal pain.

*Platinum-refractory Intolerant Locally Recurrent or Metastatic SCAC: ZYNYZ as a Single Agent*

The safety of ZYNYZ in patients with platinum-refractory intolerant locally recurrent or metastatic SCAC was evaluated in 94 patients in the POD1UM-202 trial.

Serious adverse reactions occurred in 40% of patients receiving ZYNYZ. The most frequent serious adverse reactions (≥ 2% of patients) were non-urinary tract infection, perineal pain, abdominal pain, anemia, hemorrhage, diarrhea, pyrexia, urinary tract infection, musculoskeletal pain, and dyspnea.

Permanent discontinuation of ZYNYZ due to an adverse reaction occurred in 4.3% of patients. These adverse reactions included diarrhea, non-urinary tract infection, perineal pain, and rash.

Dosage interruptions due to an adverse reaction occurred in 21% of patients who received ZYNYZ. Adverse reactions that resulted in dose delay in ≥ 2% of patients who received ZYNYZ were non-urinary tract infection, rash, diarrhea, abdominal pain, hemorrhage, musculoskeletal pain, pyrexia, and urinary tract infection.

The most common (≥ 10%) adverse reactions that occurred in patients receiving ZYNYZ were fatigue, musculoskeletal pain, diarrhea, non-urinary tract infections, perineal pain, hemorrhage, urinary tract infection, rash, nausea, decreased appetite, constipation, abdominal pain, dyspnea, pyrexia, vomiting, cough, pruritus, hypothyroidism, headache, and decreased weight.

**Please see the Full Prescribing Information.**

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