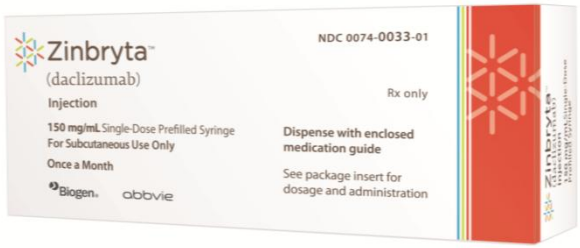
Zinbryta

(daclizumab)



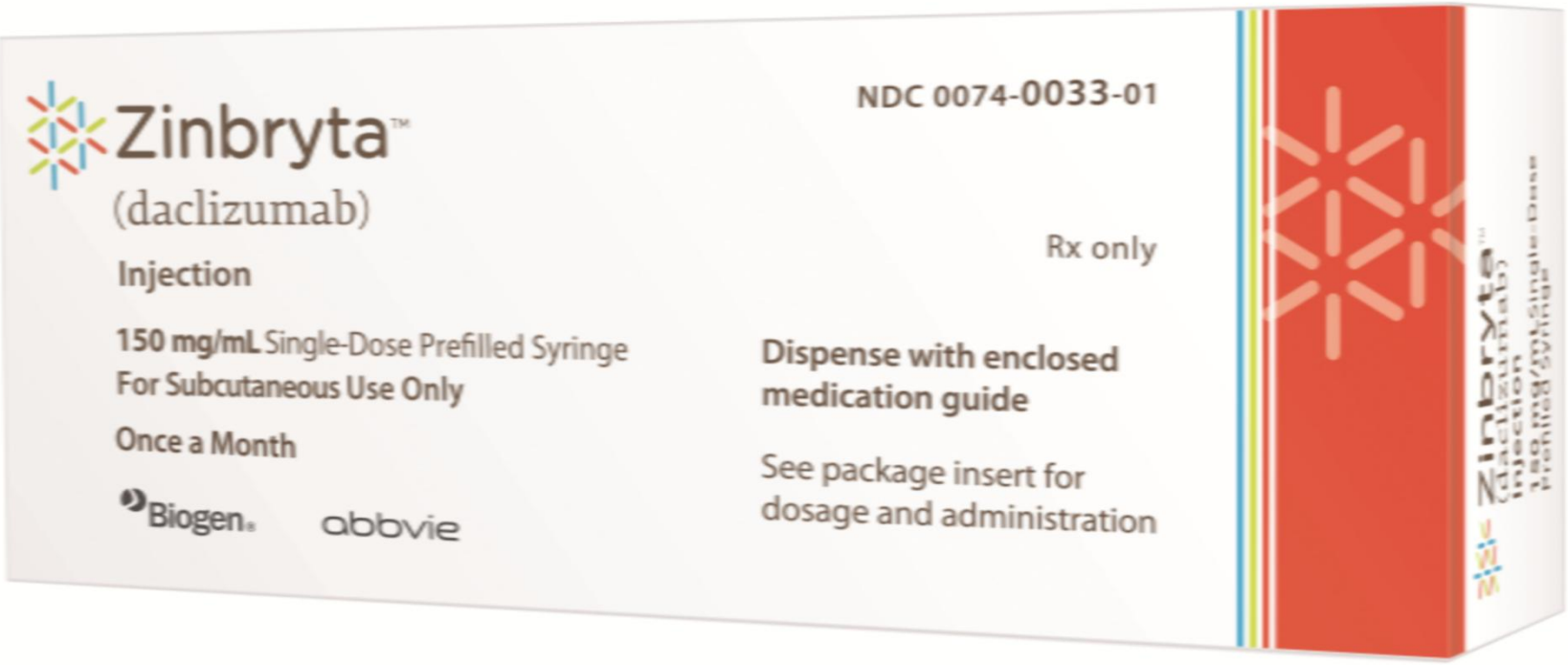
New Product Slideshow

MPR

Introduction

- **Brand name:** Zinbryta
- **Generic name:** Daclizumab
- **Pharmacological class:** Interluekin-2 (IL-2) receptor blocking antibody
- **Strength and Formulation:** 150mg/mL; solution for SC injection
- **Manufacturer:** Abbvie and Biogen
- **How supplied:** Single-dose prefilled syringe—1
- **REMS:** Yes
- **Legal Classification:** Rx

ZINBRYTA


Zinbryta™
(daclizumab)
Injection
150 mg/mL Single-Dose Prefilled Syringe
For Subcutaneous Use Only
Once a Month
Biogen
abbvie
NDC 0074-0033-01
Rx only
Dispense with enclosed medication guide
See package insert for dosage and administration

Indications

- Treatment of relapsing forms of **multiple sclerosis**

Dosage & Administration

- Give as SC injection in the thigh, abdomen, or back of upper arm
- **≥17yrs:** 150mg once monthly
- If AST/ALT >5XULN or total bilirubin >2XULN or ALT/AST ≥3–<5XULN and total bilirubin >1.5–<2XULN, interrupt or discontinue dose as appropriate (see full labeling)

Considerations for Special Populations

- **Pregnancy:** No adequate data on the developmental risk associated with use
- **Nursing mothers:** Consider clinical need and potential adverse effects
- **Pediatric:** <17yrs: not recommended
- **Geriatric:** Insufficient number studied
- **Hepatic impairment:** May increase risk for hepatotoxicity

Contraindications

- Pre-existing hepatic disease or hepatic impairment, including ALT or AST ≥2XULN
- History of autoimmune hepatitis or other autoimmune condition involving the liver

Warnings/Precautions

- **Risk of serious hepatic injury**, including autoimmune hepatitis (discontinue if suspected) and other immune-mediated disorders (eg, skin reactions, lymphadenopathy, non-infectious colitis); may require systemic corticosteroids or immunosuppressants; consider discontinuing if serious immune-mediated disorders develop
- Evaluate for TB (esp. high-risk patients); treat prior to initiation
- Screen for hepatitis B and C prior to initiation

Warnings/Precautions

- TB or other severe active infection: **avoid** starting treatment until controlled
- If serious infection develops, consider withholding until resolved
- Obtain serum ALT/AST and total bilirubin prior to initiation, at monthly intervals, and before the next dose, then follow for 6 months after last dose

Warnings/Precautions

- Eczema
- Psoriasis
- Depressive disorders
- **Monitor** for new or worsening symptoms of depression and/or suicidal ideation; consider discontinuing if severe
- **Discontinue** if anaphylaxis or allergic reactions occur; do not restart

Interactions

- **Avoid** live virus vaccines during and up to 4 months after discontinuation
- **Caution** with concomitant hepatotoxic drugs, including non-prescription products (eg, herbals, dietary supplements)

Adverse Reactions

- Nasopharyngitis
- Upper RTI
- Rash
- Influenza
- Dermatitis
- Oropharyngeal pain
- Bronchitis
- Eczema
- Lymphadenopathy
- Depression
- Increased ALT
- Hepatic injury
- Immune-mediated disorders
- Suicide

Mechanism of Action

- The precise mechanism by which daclizumab exerts its therapeutic effects in multiple sclerosis is unknown
- However, it is presumed to involve modulation of IL-2 mediated activation of lymphocytes through binding to CD25, a subunit of the high-affinity IL-2 receptor

Clinical Trials

- The efficacy of Zinbryta 150mg once every 4 weeks was evaluated in 2 randomized, double-blind, controlled studies **(Studies 1 and 2)** in patients with relapsing multiple sclerosis

Clinical Trials

- **Study 1** (n=1,841) compared Zinbryta to Avonex 30mcg once weekly
- Assessments occurred every 12 weeks and post-relapse events
- The primary outcome was **annualized relapse rate (ARR)**

Clinical Trials

- Zinbryta had a statistically significant effect on ARR and on the number of new or newly enlarging T2 hyperintense lesions

- The Zinbryta group had a 45% relative reduction in ARR ($P<0.0001$) with 67% of patients relapse free vs. 51% in the Avonex group at 144 weeks

Clinical Trials

- **Study 2** (n=412) compared Zinbryta to placebo for 52 weeks
- Assessments occurred every 12 weeks and post-relapse events
- The primary outcome was **ARR at Week 52**

Clinical Trials

- Zinbryta had a statistically significant effect on ARR, the proportion of relapse free patients, the number of new T1 Gd-enhancing lesions, and the number of new or newly enlarging T2 hyperintense lesions
- The Zinbryta group had a 54% relative reduction in ARR ($P<0.0001$) with 81% of patients relapse free vs. 64% in the placebo group at 52 weeks
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

- http://www.empr.com/zinbryta/drug/34573/