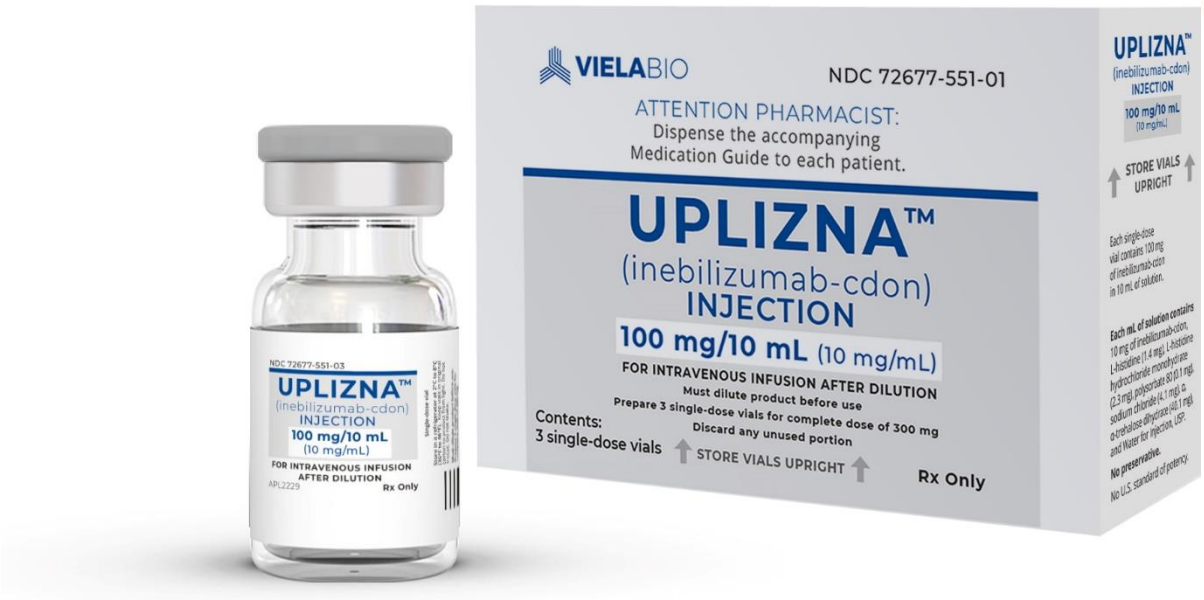
Uplizna (inebilizumab-cdon)



NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Uplizna
- **Generic name:** Inebilizumab-cdon
- **Pharmacologic class:** CD19-directed cytolytic antibody
- **Strength and Formulation:** 10mg/mL; solution for IV infusion after dilution; preservative-free
- **Manufacturer:** Viela Bio, Inc
- **How supplied:** Single-dose vials (10mL)—3
- **Legal Classification:** Rx

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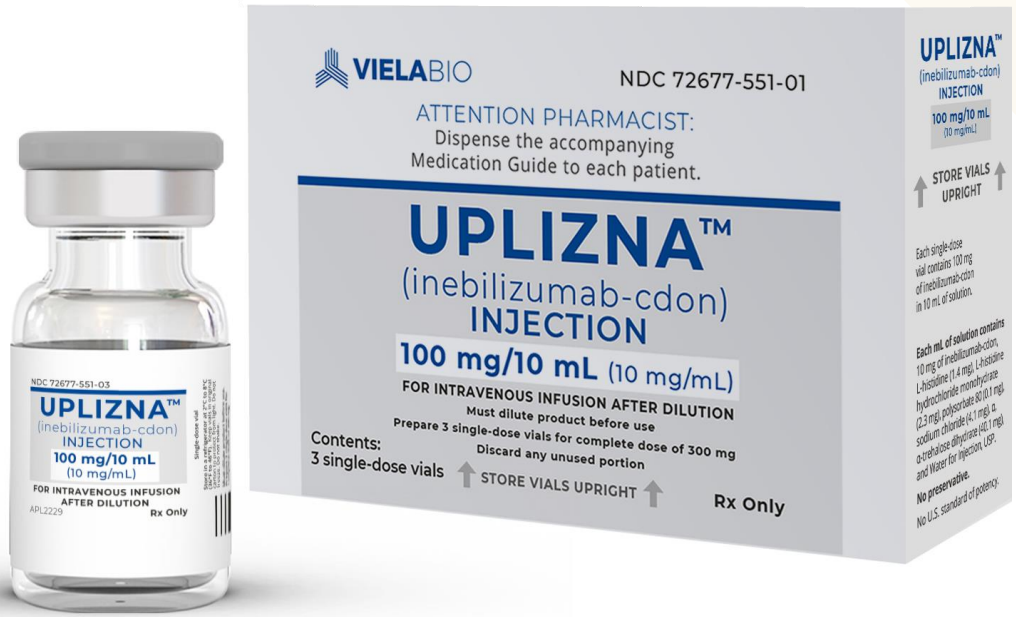
Uplizna


NDC 72677-551-03
UPLIZNA™
(inebilizumab-cdon)
INJECTION
100 mg/10 mL
(10 mg/mL)
FOR INTRAVENOUS INFUSION
AFTER DILUTION
Rx Only
APL2229
VIELABIO
NDC 72677-551-01
ATTENTION PHARMACIST:
Dispense the accompanying
Medication Guide to each patient.
UPLIZNA™
(inebilizumab-cdon)
INJECTION
100 mg/10 mL (10 mg/mL)
FOR INTRAVENOUS INFUSION AFTER DILUTION
Must dilute product before use
Prepare 3 single-dose vials for complete dose of 300 mg
Discard any unused portion
Contents:
3 single-dose vials
STORE VIALS UPRIGHT
Rx Only
UPLIZNA™
(inebilizumab-cdon)
INJECTION
100 mg/10 mL
(10 mg/mL)
STORE VIALS
UPRIGHT
Each single-dose
vial contains 100 mg
of inebilizumab-cdon
in 10 mL of solution.
Each mL of solution contains
10 mg of inebilizumab-cdon,
L-histidine (1.4 mg), L-histidine
hydrochloride monohydrate
(2.3 mg), polysorbate 80 (0.1 mg),
sodium chloride (4.1 mg), α,
α-trehalose dihydrate (68.1 mg),
and Water for Injection, USP.
No preservative.
No U.S. standard of potency.

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Indication

- Treatment of **neuromyelitis optica spectrum disorder** (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive.

Dosage and Administration

- Premedicate with a corticosteroid (IV), an antihistamine (oral), and an antipyretic (oral) prior to each infusion.
- Give by IV infusion via an infusion pump at an increasing rate to completion (approx. 90mins); see full labeling.
- **Initial dose**: 300mg, followed by a second 300mg infusion 2 weeks later.
- **Subsequent doses** (starting 6 months from 1st infusion): single 300mg every 6 months

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Considerations for Special Populations

- **Pregnancy:** No adequate data on risk; may cause fetal harm based on animal data.
- **Nursing mothers**: No data regarding presence in human milk.
- **Females of reproductive potential**: Use effective contraception during and for at least 6 months after the last dose.
- **Pediatric**: Not established.
- **Geriatric:** Did not include sufficient numbers of patients aged 65 and over to determine difference in response.

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Contraindications

- Active hepatitis B infection
- Active or untreated latent tuberculosis
- History of life-threatening infusion reaction to Uplizna

Warnings and Precautions

- Monitor for infusion reactions during and ≥1hr after therapy completion; permanently discontinue if life-threatening infusion reactions occur; treat appropriately.
- Increased risk of infections.
- Assess for infections prior to every infusion; if active, delay Uplizna treatment until resolved.
- Risk of HBV reactivation.
- Perform HBV screening in all patients prior to initiation.

Warnings and Precautions

- Monitor quantitative serum immunoglobulins before initiating, during and until B-cell repletion after discontinuation; consider discontinuing if low immunoglobulin G or M with a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires IV immunoglobulins.
- Withhold at first sign/symptom of progressive multifocal leukoencephalopathy (PML) and evaluate.
- Evaluate for TB risks and test/treat latent TB prior to initiation.

Warnings and Precautions

- Complete all immunizations according to guidelines ≥4 weeks prior to treatment.
- Infants born to mothers treated during pregnancy: do not administer live or live-attenuated vaccines before confirming B-cell recovery in the infant; non-live vaccines may be given prior to recovery, but should consider assessment of vaccine immune response.

Interactions

- Concomitant live or live-attenuated vaccines: not recommended during treatment and until B-cell repletion.
- Additive immunosuppressive effects with other immunosuppressants including systemic corticosteroids.

Adverse Reactions

- **Most common (> 10%)**: Urinary tract infection, nasopharyngitis, infusion reaction, arthralgia, headache
- **Others**: Lab abnormalities (decreased immunoglobulins, lymphocytes, and neutrophils)

Mechanism of Action

- Precise mechanism by which inebilizumab-cdon exerts its therapeutic effects is unknown.
- Presumed to involve binding to CD19, a cell surface antigen present on pre-B and mature B lymphocytes.
- Following cell surface binding to B lymphocytes, inebilizumab-cdon results in antibody-dependent cellular cytolysis.

Pharmacokinetics

- Mean terminal half-life: 18 days
- Metabolized by proteolytic enzymes widely distributed in the body

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Clinical Trials

- Efficacy of Uplizna was established in a randomized, double-blind, placebo-controlled trial (NCT02200770) that included 213 patients with NMOSD who were anti-AQP4 antibody positive and 17 who were anti-AQP4 antibody negative.
- Eligibility criteria included:
  - A history of 1 or more relapses that required rescue therapy within the year prior to screening, or 2 or more relapses that required rescue therapy in 2 years prior to screening.
  - Expanded Disability Status Scale (EDSS) score of 7.5 or less. Patients with an EDSS score of 8.0 were eligible if they were deemed capable of participating.
  - Patients were excluded if previously treated with immunosuppressant therapies within an interval specified for each such therapy.

Clinical Trials

- **Patient demographics**
  - Mean age: 43 years (range 18 to 74 years)
  - 94% female; 52% White; 21% Asian, and 9% Black or African American
  - Mean EDSS score: 4.0
  - Number of relapses in the 2 years prior to randomization was 2 or more in 83% of the patients

Clinical Trials

- Patients were randomized 3:1 to receive 2 intravenous (IV) doses of Uplizna (n=161) or placebo (n=52) among the anti-AQP4 antibody positive population.
- The **primary efficacy end point** was the time to the onset of the first adjudicated relapse on or before day 197

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Clinical Trials

- Results showed that the time to the first adjudicated relapse was significantly longer in patients treated with Uplizna compared with placebo (relative risk reduction 73%; hazard ratio [HR] 0.272; *P* <.0001).
- In the anti-AQP4 antibody positive population, there was a 77.3% relative risk reduction in patients treated with Uplizna compared with placebo (HR 0.227; 95% CI, 0.121-0.423; *P* <.0001).
  - Number (%) of patients with relapse: 18 (11.2%) in the Uplizna group vs 22 (42.3%) in the placebo group.

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Clinical Trials

- There was no evidence of a benefit in patients who were anti-AQP4 antibody negative.
- Compared with placebo-treated patients, patients treated with Uplizna who were anti-AQP4 antibody positive had reduced annualized rates of hospitalizations (0.11 vs 0.50).

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/uplizna/