Ocrevus

(ocrelizumab)

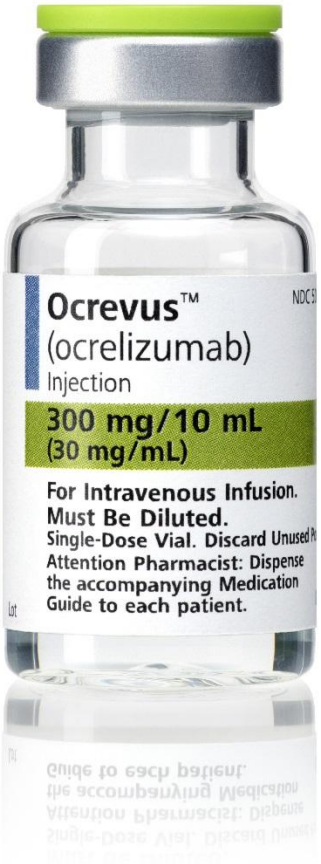
New Product
Slideshow

MPR

Introduction

- **Brand name:** Ocrevus
- **Generic name:** Ocrelizumab
- **Pharmacological class:** CD20-directed cytolytic monoclonal antibody
- **Strength and Formulation:** 30mg/mL; soln for IV infusion after dilution; preservative-free
- **Manufacturer:** Genentech
- **How supplied:** Single-dose vial (10mL)—1
- **Legal Classification:** Rx

Ocrevus


Ocrevus™
(ocrelizumab)
Injection
300 mg/10 mL
(30 mg/mL)
For Intravenous Infusion.
Must Be Diluted.
Single-Dose Vial. Discard Unused
Attention Pharmacist: Dispense
the accompanying Medication
Guide to each patient.

Indications

- Relapsing or primary progressive forms of **multiple sclerosis**

Dosage & Administration

- Screen for HBV infection prior to initiation
- **Premedicate** with corticosteroid and antihistamine prior to each infusion; may consider antipyretic
- **Initially** 300mg by IV infusion, followed by a second 300mg infusion 2 weeks later, then subsequently as one 600mg infusion every 6 months
- For infusion rates, duration, and dose modifications: see full labeling

Considerations for Special Populations

- **Pregnancy:** No adequate data on the developmental risk associated with use of Ocrevus
- **Nursing mothers:** Consider benefits of breastfeeding and any potential adverse effects
- **Pediatric:** Not established
- **Elderly:** Insufficient number of subjects studied

Contraindications

- Active HBV infection

Warnings/Precautions

- **Monitor** for infusion reactions during therapy and at least 1hr after completion; permanently discontinue if life-threatening infusion reactions occur; treat appropriately
- **Active infection**; delay Ocrevus treatment until resolved
- **Withhold** at first sign/symptom of progressive multifocal leukoencephalopathy (PML) and evaluate

Warnings/Precautions

- **HBV reactivation:** test all patients for HBV; if positive HBsAg/anti-HB results, do not administer Ocrevus
- Increased risk of **malignancy** (including breast cancer)
- Complete all **immunizations** according to guidelines at least 6 weeks prior to initiation
- **Females of reproductive potential** should use effective contraception during and for 6 months after last dose

Interactions

- Concomitant **live or live-attenuated vaccines:** not recommended during treatment and until B-cell repletion
- Additive immunosuppressive effects with other **immunosuppressants**; consider the duration and effects when switching from immunomodulators (eg, corticosteroids, daclizumab, fingolimod, natalizumab, teriflunomide, mitoxantrone)

Adverse Reactions

- Upper/lower respiratory tract infections
- Infusion reactions (eg, pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, others)
- Skin infections
- Herpes virus-associated infections

Mechanism of Action

- The mechanism by which ocrelizumab exerts its therapeutic effects in multiple sclerosis is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes
- Following cell surface binding to B lymphocytes, it results in antibody-dependent cellular cytolysis and complement-mediated lysis

Clinical Trials

- Ocrevus was studied in 2 randomized, double-blind, double-dummy, active comparator-controlled clinical trials in patients with RMS treated for 96 weeks (**Study 1 and Study 2**)
- Ocrevus 600mg was given every 24 weeks and placebo subcutaneous injections were given 3 times weekly
- Rebif 44mcg, the active comparator, was given 3 times weekly and placebo IV infusions were given every 24 weeks

Clinical Trials

- The **primary outcome** of Study 1 and Study 2 was the annualized relapse rate (ARR)
- Other outcome measure included:
  - Proportion of patients with confirmed disability progression
  - Mean number of MRI T1 gadolinium (Gd)-enhancing lesions at Weeks 24, 48, 96
  - New or enlarging MRI T2 hyperintense lesions

Clinical Trials

- In Study 1 (n=821) and Study 2 (n=835), Ocrevus **significantly lowered the ARR** and the proportion of patients with disability progression confirmed at 12 weeks after onset vs. Rebif

Clinical Trials

- In **Study 1**, there was a 46% relative reduction in ARR ($P<0.0001$) when comparing the Ocrevus vs. Rebif treatment arms
  - 83% of Ocrevus patients were relapse-free vs. 71% of Rebif patients
- In **Study 2**, there was a 47% relative reduction in ARR ($P<0.0001$) when comparing the Ocrevus vs. Rebif treatment arms
  - 82% of Ocrevus patients were relapse-free vs. 72% of Rebif patients

Clinical Trials

- Across both studies, there were less Ocrevus-treated patients with 12-week confirmed disability progression than Rebif-treated patients (9.8% vs. 15.2%)
  - The risk reduction in the pooled analysis was **40%** (*P*=0.0006)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/ocrevus/drug/34660/