Cinqair

(reslizumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Cinqair
- **Generic name:** Reslizumab
- **Pharmacological class:** Interleukin-5 antagonist
- **Strength and Formulation:** 100mg/10mL; solution for IV infusion; preservative-free
- **Manufacturer:** Teva
- **How supplied:** Single-use vial—1
- **Legal Classification:** Rx

CINQAIR


NDC 59310-610-31
Must be Refrigerated
Rx only
Sterile
CINQAIR®
(reslizumab)
Injection
100 mg/10 mL
(10 mg/mL)
For Intravenous Infusion Only
Dilute Prior to Administration
One Single-Use Vial
Discard Unused Portion
TEVA
NDC 59310-610-31
CINQAIR®
(reslizumab)
Injection
100 mg/10 mL
(10 mg/mL)
For Intravenous Infusion Only
Dilute Prior to Administration
Single-Use Vial
Discard Unused Portion

Indications

- As add-on maintenance treatment of severe asthma in patients ≥18 years old, and with an eosinophilic phenotype

- **Limitations of use:**
  - Not for treating other eosinophilic conditions
  - Not for relief of acute bronchospasm or status asthmaticus

Dosage & Administration

- Give by IV infusion over 20–50 minutes
- ≥18 years: 3mg/kg once every 4 weeks

Considerations for Special Populations

- **Pregnancy:** Data insufficient to inform on drug-associated risk
- **Nursing mothers:** Presence in human milk unknown
- **Pediatric:** <18 years: not established
- **Geriatric:** No overall differences were observed
- **Hepatic impairment:** No studies conducted
- **Renal impairment:** No studies conducted

Warnings/Precautions

- Should be administered by healthcare provider **prepared to manage anaphylaxis**
- **Observe patient** for a period of time post-infusion; discontinue immediately if severe systemic reactions or anaphylaxis occur
- Not for treating acute asthma symptoms or exacerbations

Warnings/Precautions

- Treat pre-existing **helminth infections** before initiating therapy; discontinue Cinqair if treatment-resistant infection occurs while on therapy until resolves
- **Avoid abrupt cessation** of systemic or inhaled corticosteroids upon Cinqair initiation; reduce dose gradually if appropriate.
- Reduction may be associated with **systemic withdrawal symptoms** and/or unmask previously suppressed conditions

Adverse Reactions

- Oropharyngeal pain
- Elevated CPK
- Myalgia
- Anaphylaxis
- Malignancy

Mechanism of Action

- Reslizumab is an **interleukin-5 antagonist** (IgG4, kappa)
- It inhibits the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil surface
- Reslizumab reduces the production and survival of eosinophils; however, the mechanism of its action in asthma has not been definitively established

Pharmacokinetics

- **Distribution:** volume of distribution ~5L; minimal distribution to extravascular tissues
- **Metabolism:** degraded by enzymatic proteolysis into small peptides and amino acids
- **Elimination:** Clearance ~7mL/hr; half-life ~24 days

Clinical Trials

- The asthma developmental program for Cinqair 3mg/kg included **4 randomized, double-blind, placebo-controlled studies** (Studies I–IV) 16–52 weeks in duration involving a total of 981 patients aged ≥12 years old
- **Studies I and II** were 52-week studies in 953 patients with asthma who were required to have a blood eosinophil count ≥400/mcL and ≥1 asthma exacerbation requiring systemic corticosteroid use over the past 12 months

Clinical Trials

- The **primary endpoint** was the frequency of asthma exacerbations during the 52-week treatment period
- Patients receiving Cinqair 3mg/kg once every 4 weeks had **significant reductions** in the rate of all asthma exacerbations vs. placebo (**Study I**: 0.5 [95% CI: 0.37, 0.67]; **Study II**: 0.41 [95% CI: 0.28, 0.59])
- Exacerbations requiring systemic corticosteroid use was also reduced in the Cinqair group vs. placebo (**Study I**: 0.45 [95% CI: 0.33, 0.62]; **Study II**: 0.39 [95% CI: 0.27, 0.58])

Clinical Trials

- Exacerbations resulting in a **hospitalization and/or ER visit** was also reduced in the Cinqair group vs. placebo (Study I: 0.66 [95% CI: 0.32, 1.36]; Study II: 0.69 [95% CI: 0.29, 1.65])
- The **time to first asthma exacerbation** was significantly longer for the Cinqair groups vs. placebo in both studies

Clinical Trials

- **Study III** was a 16-week study in 315 patients with a blood eosinophil count ≥400/mcL at screening; maintenance oral corticosteroids were not allowed
- **Study IV** was a 16-week study in 496 patients unselected for baseline blood eosinophil levels; maintenance oral corticosteroids were not allowed
- The **primary endpoint** for Studies III and IV was change in FEV1

Clinical Trials

- Also, Study III examined a lower dose, Cinqair 0.3mg/kg, which produced significant but numerically smaller changes in FEV1 and blood eosinophil reduction vs. the 3mg/kg dose.

- The effect of Cinqair 3mg/kg on FEV1 over time relative to placebo was assessed in all 4 studies

Clinical Trials

- Over 16 weeks, the **mean change from baseline in FEV1** (difference from Cinqair and placebo) was 137mL (95% CI: 76, 198) in **Study I**, 93mL (95% CI: 30, 155) in **Study II**, 160mL (95% CI: 60, 259) in **Study III**, and 76mL (95 % CI: −6, 158) in **Study IV**
- Improvements in FEV1 were seen at 4 weeks after the first Cinqair dose for Studies I and II, and maintained through Week 52
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/cinqair/drug/34551/