Taltz

(ixekizumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Taltz
- **Generic name:** Ixekizumab
- **Pharmacological class:** Interleukin-17A antagonist
- **Strength and Formulation:** 80mg/mL; soln for SC inj; preservative-free
- **Manufacturer:** Eli Lilly
- **How supplied:** Single-dose prefilled autoinjector—1, 2, 3; Single-dose prefilled syringe—1, 2, 3
- **Legal Classification:** Rx

TALTZ


open here
taltz
(ixekizumab)
injection
80 mg/mL
1 Single-Dose prefilled syringe
For Subcutaneous Use Only
Single-Dose Only
Each prefilled syringe contains 80 mg of TALTZ.
Rx Only
Dispense enclosed Medication Guide to each patient.
Lilly
open here
taltz
(ixekizumab)
injection
80 mg/mL
1 Single-Dose prefilled autoinjector
For Subcutaneous Use Only
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Rx Only
Dispense enclosed Medication Guide to each patient.
Lilly

Indications

- Moderate-to-severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy

Dosage & Administration

- Rotate injection site (eg, upper arms, thighs, or any quadrant of abdomen)
- **≥18yrs:** 160mg (given as two 80mg SC injections) at Week 0, then 80mg at Weeks 2, 4, 6, 8, 10, and 12, then 80mg every 4 weeks

Considerations for Special Populations

- **Pregnancy:** No available data
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** <18yrs: not evaluated
- **Geriatric:** Insufficient number studied
- **Hepatic or renal impairment:** No formal trial of the effects on ixekizumab pharmacokinetics conducted

Warnings/Precautions

- Increased risk of infections
- If a **serious infection** develops, monitor closely and discontinue until resolves
- Evaluate for TB infection and treat latent TB prior to initiating; monitor for active TB during and after therapy
- Active TB infection: do not start
- History of latent or active TB without confirmed adequate course of treatment: consider anti-TB therapy prior to initiation

Warnings/Precautions

- Monitor for **inflammatory bowel disease**
- **Discontinue immediately** and treat if a serious hypersensitivity reaction occurs
- Complete all age appropriate immunizations based on current guidelines prior to initiating

Interactions

- Concomitant **live vaccines**: not recommended

- Monitor **CYP450 substrates** with narrow therapeutic index (eg, warfarin, cyclosporine); consider dose adjustment of these substrates

Adverse Reactions

- Injection site reactions
- Upper respiratory tract infections
- Nausea
- Tinea infections

Mechanism of Action

- Ixekizumab is a humanized immunoglobulin G subclass 4 (IgG4) monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor
- IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses
- Ixekizumab inhibits the release of proinflammatory cytokines and chemokines

Clinical Trials

- **Trials 1, 2, and 3** were multicenter, randomized, double-blind, placebo-controlled studies that enrolled 3,866 subjects aged ≥18yrs with plaque psoriasis who:
  - Had minimum body surface area involvement of 10%
  - Had static Physician Global Assessment (sPGA) score ≥3 in the overall assessment of psoriasis on a severity scale of 0−5
  - Had Psoriasis Area and Severity Index (PASI) score ≥12
  - Were candidates for phototherapy or systemic therapy
- Subjects had a median baseline PASI score of approximately 17−18

Clinical Trials

- In all 3 trials, subjects were randomized to either placebo or Taltz 80mg every 2 weeks for 12 weeks, with a 160mg initial dose
- In Trials 2 and 3, subjects were also randomized to receive etanercept 50mg twice weekly for 12 weeks
- All 3 trials assessed the changes from baseline to Week 12 in PASI 75, the proportion of subjects achieving ≥75% reduction in PASI composite score, and sPGA of "0" (clear) or "1" (minimal) and at least a 2-point improvement

Clinical Trials

- In **Trial 1**, PASI 75 was achieved in 89% of patients in the Taltz arm vs. 4% in the placebo arm
- Also, PASI 90 was 71% in the Taltz arm vs. 1% in placebo and PASI 100 was 35% in the Taltz arm vs. 0% in placebo
- A sPGA of "0" or "1" was achieved in 82% of patients in the Taltz arm vs. 3% in placebo

Clinical Trials

- In **Trial 2**, PASI 75 was achieved in 90% of patients in the Taltz arm vs. 2% in the placebo arm
- Also, PASI 90 was 71% in the Taltz arm vs. 1% in placebo and PASI 100 was 40% in the Taltz arm vs. 1% in placebo
- A sPGA of "0" or "1" was achieved in 83% of patients in the Taltz arm vs. 2% in placebo

Clinical Trials

- In **Trial 3**, PASI 75 was achieved in 87% of patients in the Taltz arm vs. 7% in the placebo arm
- Also, PASI 90 was 68% in the Taltz arm vs. 3% in placebo and PASI 100 was 38% in the Taltz arm vs. 0% in placebo
- A sPGA of "0" or "1" was achieved in 81% of patients in the Taltz arm vs. 7% in placebo
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/taltz/drug/34558/