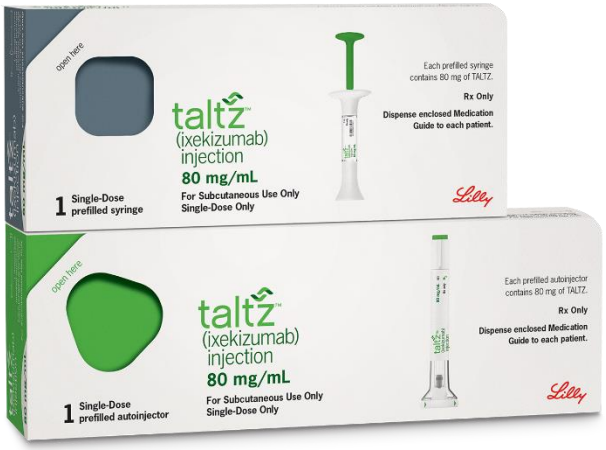
Taltz (ixekizumab)



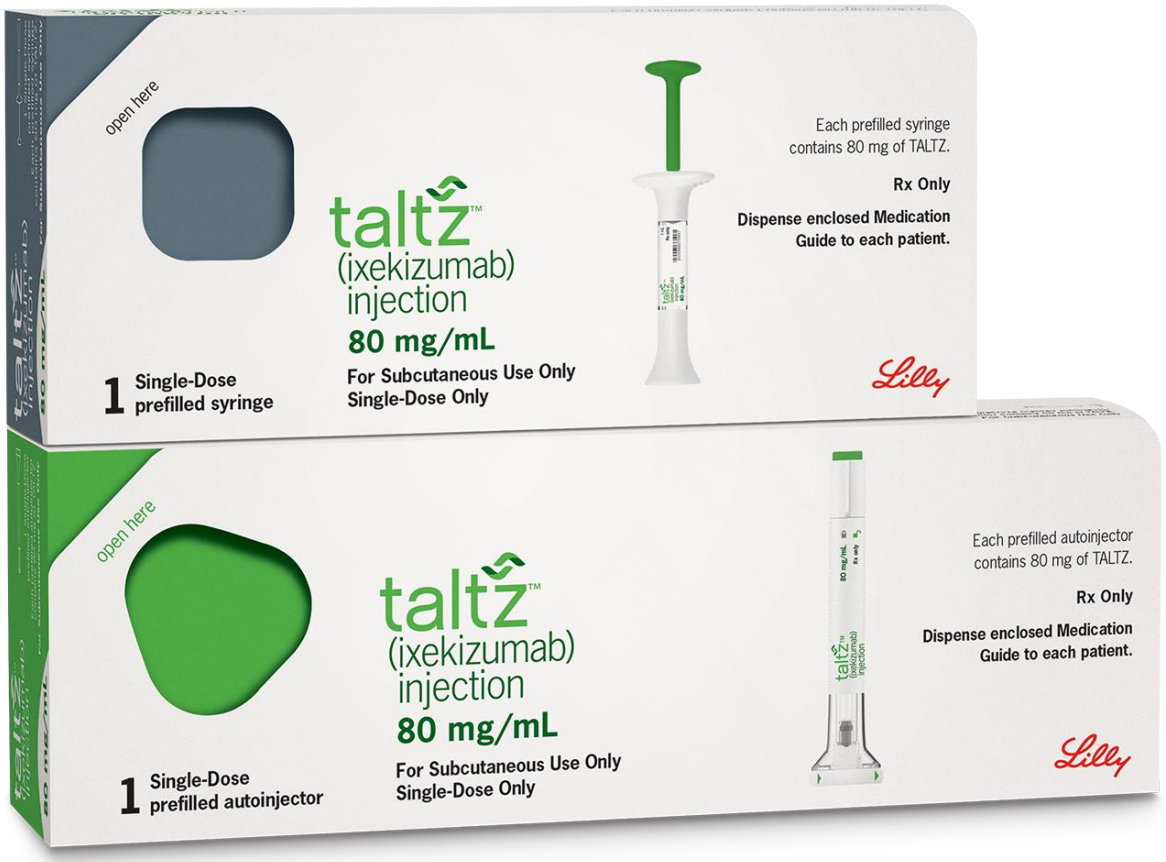
NEW INDICATION REVIEW

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-use prefilled autoinjector—1, 2, 3; Single-use prefilled syringe—1
- **Legal Classification:** Rx

Taltz


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

New Indication

- **Active psoriatic arthritis**

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

Dosage & Administration

- **Active psoriatic arthritis**
  - May be given alone or in combination with a conventional DMARD
  - Rotate inj site (eg, upper arms, thighs, or any quadrant of abdomen)
  - **≥18yrs:** 160mg (given as two 80mg SC injections) at Week 0, then 80mg every 4 weeks
  - **With coexistent plaque psoriasis:** 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

  - *See full labeling for additional dosing information*

Considerations for Special Populations

- **Pediatric:** <18yrs: not evaluated
- **Pregnancy:** Insufficient human data to establish drug-associated risk
- **Nursing mothers:** Consider mother's need and potential adverse effects on child
- **Elderly:** No differences in safety or efficacy observed

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

- **Avoid** concomitant live vaccines
- 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 IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor
- This inhibits the release of pro-inflammatory cytokines and chemokines

Clinical Studies

- The safety and efficacy of Taltz were evaluated in 2 randomized, double-blind placebo-controlled studies **(PsA1 and PsA2)** in adults with active psoriatic arthritis despite NSAID, corticosteroid or DMARD therapy

Clinical Studies

- **PsA1** (n=417) included biologic-naïve patients who were given either Taltz 160mg at Week 0 followed by 80mg every 2 weeks (Q2W) or every 4 weeks (Q4W), adalimumab 40mg every 2 weeks, or placebo
- **PsA2** (n=363) included anti-TNF-alpha experienced patients who were given Taltz 160mg at Week 0 followed by 80mg every 2 or 4 weeks, or placebo

Clinical Studies

- The **primary endpoint** was the percentage of patients achieving an ACR20 response at Week 24
- In both studies, patients treated with Taltz 80mg Q2W or Q4W showed a greater clinical response including ACR20, ACR50, and ACR70 vs placebo at Week 24

Clinical Studies

- PsA1
  - ACR20: 58% (Taltz Q4W) vs 30% (placebo)
  - ACR50: 40% vs 15%
  - ACR70: 23 % vs 6%
- PsA2
  - ACR20: 53% (Taltz Q4W) vs 20% (placebo)
  - ACR50: 35% vs 5%
  - ACR70: 22% vs 0%

Clinical Studies

- In **PsA2**, responses were seen regardless of prior anti-TNF-alpha exposure
- Treatment with Taltz led to **improved dactylitis** and **enthesitis** in patients with pre-existing dactylitis or enthesitis
- Taltz 80mg Q4W led to **improved psoriatic skin lesions** in patients with PsA

Clinical Studies

- Taltz 80mg Q4W also inhibited the progression of **structural joint damage** (mTSS) vs placebo at Week 16 (difference from placebo -0.23, 95% CI: -0.42, -0.04)
- The proportion of **HAQ-DI responders** in both studies was greater in the Taltz 80mg Q4W group vs placebo at Week 12 and 24

Clinical Studies

- At Week 12, Taltz-treated patients showed greater improvement from baseline in the **SF-36 physical component summary** (PCS) score vs placebo in both studies
  - Improvement was not consistent for the SF-36 mental component summary (MCS) score
- For more clinical data, see full labeling

Product Monograph

- For more information view the product monograph available at:

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