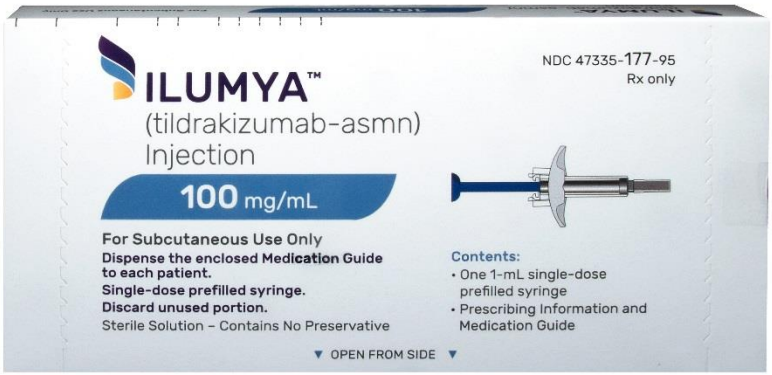
Ilumya (tildrakizumab-asmn)



NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Ilumya
- **Generic name:** Tildrakizumab-asmn
- **Pharmacological class:** Interleukin-23 antagonist
- **Strength and Formulation:** 100mg/mL; soln for SC inj; preservative-free
- **Manufacturer:** Sun Pharmaceutical Industries
- **How supplied:** Single-dose prefilled syringe-1 (w. needle guard + cover)
- **Legal Classification:** Rx

Ilumya


ILUMYA™
(tildrakizumab-asmn)
Injection
100 mg/mL
For Subcutaneous Use Only
Dispense the enclosed Medication Guide to each patient.
Single-dose prefilled syringe.
Discard unused portion.
Sterile Solution – Contains No Preservative
NDC 47335-177-95
Rx only
Contents:
• One 1-mL single-dose prefilled syringe
• Prescribing Information and Medication Guide
▼ OPEN FROM SIDE ▼

Indication

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

Dosage & Administration

- Give by SC inj in abdomen, thighs, or upper arm
- **≥18yrs:** 100mg at weeks 0 and 4, then every 12 weeks thereafter

Considerations for Special Populations

- **Pregnancy:** Limited data with Ilumya use in pregnant women to inform drug associated risk
- **Nursing mothers:** Consider mother's clinical need with potential adverse effects on breastfed child
- **Pediatric:** <18yrs: not established
- **Elderly:** No differences in safety and efficacy observed

Warnings/Precautions

- Should only be administered by a healthcare provider
- Discontinue if serious hypersensitivity reaction occurs, treat appropriately
- May increase risk of infections
- Chronic or history of recurrent infection: consider the risks and benefits

Warnings/Precautions

- Evaluate for tuberculosis (TB) infection and treat latent TB prior to initiating
- Monitor for signs/symptoms of active TB during and after therapy
- Patients with active TB infection: do not initiate
- History of latent or active TB (without confirmed adequate treatment); consider anti-TB therapy prior to initiation
- Consider completion of all age appropriate immunizations according to current guidelines

Interactions

- Concomitant live vaccines: not recommended

Adverse Reactions

- Upper respiratory infections
- Injection site reactions
- Diarrhea
- Hypersensitivity reactions

Mechanism of Action

- Tildrakizumab is a humanized IgG1/k monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor
- IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses
- Tildrakizumab inhibits the release of pro-inflammatory cytokines and chemokines

Clinical Studies

- Ilumya was evaluated in 2 multicenter, randomized, double-blind, placebo-controlled trials (**Trial 2 and Trial 3**) in adults with moderate-to-severe plaque psoriasis (N=926)

Clinical Studies

- Patients were randomized to receive placebo or Ilumya (100mg at week 0, week 4, and every 12 weeks thereafter) for up to 64 weeks

Clinical Studies

- Co-primary endpoints:
  - **PASI 75:** proportion of subjects who achieved at least a 75% reduction in the PASI composite score at week 12
  - **PGA of 0 (cleared) or 1 (minimal):** proportion of subjects with a PGA of 0 or 1 and at least a 2-point improvement at week 12

Clinical Studies

- In Trial 2, **58%** (N=179) of patients in the Ilumya group had a PGA of 0 or 1 at Week 12, vs **7%** (N=11) in the placebo group
- Also, **64%** (N=197) of patients in the Ilumya group were PASI 75 responders at Week 12, vs **6%** (N=9) in the placebo group

Clinical Studies

- In Trial 3, **55%** (N=168) of Ilumya-treated patients achieved PGA of 0 or 1 at Week 12 vs **4%** (N=7) in the placebo group
- Patients who were PASI 75 responders included **61%** (N=188) and **6%** (N=9) in the Ilumya and placebo groups, respectively
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/ilumya/drug/34890/