

Tremfya (guselkumab)



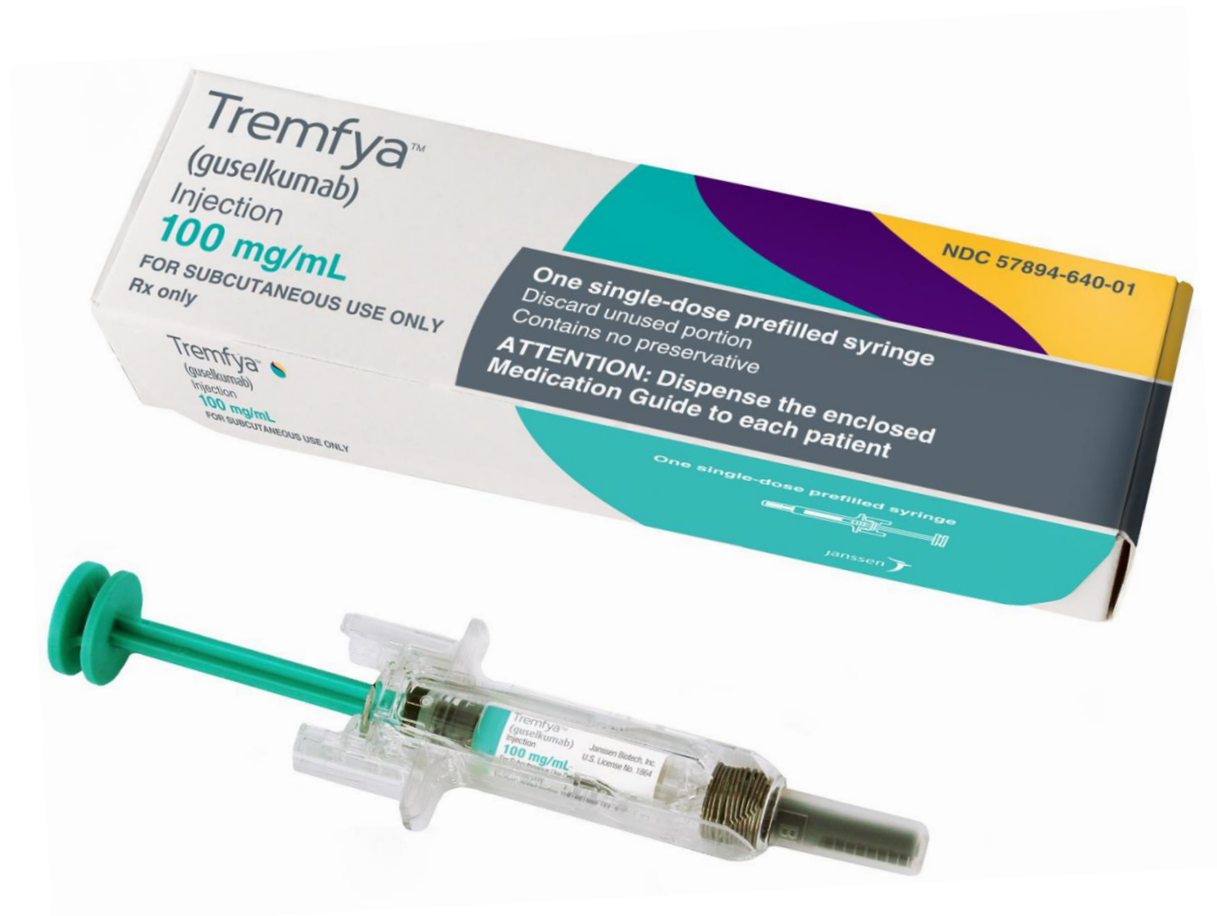
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Tremfya
- **Generic name:** Guselkumab
- **Pharmacological class:** Interleukin-23 antagonist
- **Strength and Formulation:** 100mg/mL; soln for SC inj; preservative-free
- **Manufacturer:** Janssen Biotech
- **How supplied:** Single-dose prefilled syringes—1
- **Legal Classification:** Rx

TREMFYA



Indications

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

Dosage & Administration

- Do not inject in areas where skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis
- **≥18yrs:** 100mg by SC inj at Weeks 0 and 4, then every 8 weeks thereafter

Considerations for Special Populations

- **Pregnancy:** No available data to inform drug-associated risk
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18yrs: not established
- **Elderly:** No overall differences in safety or efficacy observed

Warnings/Precautions

- Use under physician supervision
- Increased risk of infections
- Chronic or history of **recurrent infection**:
consider risks/benefits
- If a serious infection develops, monitor
closely and discontinue until resolves

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

Warnings/Precautions

- Consider completion of all age appropriate **immunizations** according to current guidelines before starting therapy

Interactions

- Concomitant **live vaccines**: not recommended
- Concomitant **CYP450 substrates** with narrow therapeutic index: monitor and adjust dose as needed

Adverse Reactions

- Upper respiratory infections
- Headache
- Inj site reactions
- Arthralgia
- Diarrhea
- Gastroenteritis
- Tinea infections
- Herpes simplex infections

Mechanism of Action

- **Guselkumab** is an interleukin-23 (IL-23) antagonist that inhibits the release of pro-inflammatory cytokines and chemokines by selectively binding to the p19 subunit of IL-23

Clinical Studies

- Tremfya was studied in 3 randomized, double-blind, multicenter studies (**VOYAGE 1, VOYAGE 2, and NAVIGATE**)
- Enrolled patients (ages ≥ 18) had moderate-to-severe plaque psoriasis and were eligible for systemic therapy
 - Patients had IGA ≥ 3 , PASI ≥ 12 , and minimum affected BSA of 10%

Clinical Studies

- VOYAGE 1 and VOYAGE 2 randomized 1,443 patients to either Tremfya 100mg (at Weeks 0, 4, and every 8 weeks thereafter), adalimumab 80mg (at Week 0, and 40mg at Week 1, then 40mg every other week thereafter), or placebo

Clinical Studies

- The **two co-primary endpoints** at Week 16 were:
 - Proportion of subjects with IGA score 0 or 1
 - Proportion of patients who achieved a $\geq 90\%$ reduction from baseline in PASI 90 score
- The **secondary endpoints** were additional comparisons between Tremfya and adalimumab

Clinical Studies

- In VOYAGE 1, the Tremfya arm was superior in achieving both IGA and PASI 90 response at Week 16 (**85%** and **73%**) vs. placebo (7% and 3%)

Clinical Studies

- In VOYAGE 2, the Tremfya arm was superior in achieving both IGA and PASI 90 response at Week 16 (**84%** and **70%**) vs. placebo (8% and 2%)

Clinical Studies

- The Tremfya group reported greater improvements in symptoms of psoriasis at Week 16 vs. placebo in both trials, according to the Psoriasis Symptoms and Signs Diary (PSSD)

Clinical Studies

- In **NAVIGATE**, 268 patients with inadequate response (IGA ≥ 2) at Week 16 after initial ustekinumab treatment were randomized either to continue ustekinumab every 12 weeks or switch to Tremfya 100mg

Clinical Studies

- A greater proportion treated with Tremfya achieved IGA 0/1 with a ≥ 2 grade improvement at Week 28 vs. patients treated with ustekinumab (**31% vs. 14%**, respectively)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/tremfya/drug/34711/>