

**Medication Guide**  
**TREMFYA® (trem fye´ ah)**  
**(guselkumab)**  
**injection, for subcutaneous use**

**What is the most important information I should know about TREMFYA?**

**TREMFYA may cause serious side effects, including:**

- **Serious allergic reactions.** Stop using TREMFYA and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching
- **Infections.** TREMFYA is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA and may treat you for TB before you begin treatment with TREMFYA if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA. Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:
  - fever, sweats, or chills
  - cough
  - shortness of breath
  - blood in your phlegm (mucus)
  - muscle aches
  - warm, red, or painful skin or sores on your body different from your psoriasis
  - weight loss
  - diarrhea or stomach pain
  - burning when you urinate or urinating more often than normal

See **“What are the possible side effects of TREMFYA?”** for more information about side effects.

**What is TREMFYA?**

TREMFYA is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light)
- with active psoriatic arthritis (PsA).

It is not known if TREMFYA is safe and effective in children under 18 years of age.

**Do not use TREMFYA** if you have had a serious allergic reaction to guselkumab or any of the other ingredients in TREMFYA. See the end of this Medication Guide for a complete list of ingredients in TREMFYA.

**Before using TREMFYA, tell your healthcare provider about all of your medical conditions, including if you:**

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about TREMFYA?”**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA.
- are pregnant or plan to become pregnant. It is not known if TREMFYA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use TREMFYA?**

**See the detailed “Instructions for Use” that comes with TREMFYA for information on how to prepare and inject a dose of TREMFYA, and how to properly throw away (dispose of) used TREMFYA prefilled syringes or One-Press injectors.**

- Use TREMFYA exactly as your healthcare provider tells you to use it.
- If you miss your TREMFYA dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Call your healthcare provider if you are not sure what to do.

If you inject more TREMFYA than prescribed, call your healthcare provider right away.

**What are the possible side effects of TREMFYA?**

**TREMFYA may cause serious side effects including:**

- See “What is the most important information I should know about TREMFYA?”

**The most common side effects of TREMFYA include:**

- upper respiratory infections
- joint pain (arthralgia)
- fungal skin infections
- headache
- diarrhea
- herpes simplex infections
- injection site reactions
- stomach flu (gastroenteritis)
- bronchitis

These are not all the possible side effects of TREMFYA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of TREMFYA**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TREMFYA for a condition for which it was not prescribed. Do not give TREMFYA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about TREMFYA that is written for health professionals.

**What are the ingredients in TREMFYA?**

**Active ingredient:** guselkumab

**Inactive ingredients:** L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection

Not made with natural rubber latex.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, U.S. License Number 1864  
For more information, call 1-800-526-7736 or go to [www.tremfya.com](http://www.tremfya.com).

This Medication Guide had been approved by the U.S. Food and Drug Administration.

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