Medication Guide

TREMFYA® (trem fye´ ah) (guselkumab) injection, for subcutaneous use	**TREMFYA® (trem fye´ ah) PEN (guselkumab) injection, for subcutaneous use**	**TREMFYA® (trem fye´ ah) (guselkumab) injection, for intravenous 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
- **Liver problems.** With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA. Your healthcare provider may stop treatment with TREMFYA if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:
  - unexplained rash
  - vomiting
  - tiredness (fatigue)
  - yellowing of the skin or the whites of your eyes
  - nausea
  - stomach pain (abdominal)
  - loss of appetite
  - dark urine

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)
- with moderately to severely active ulcerative colitis
- with moderately to severely active Crohn's disease

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. **Pregnancy Registry**: If you become pregnant during treatment with TREMFYA, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA. You can enroll in this registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. The purpose of this registry is to collect information about the safety of TREMFYA during pregnancy.
- 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) the used TREMFYA prefilled syringe, One-Press injector or prefilled pen (TREMFYA PEN).

- 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.
- Adults with plaque psoriasis or psoriatic arthritis will receive TREMFYA as an injection under the skin (subcutaneous injection).
- Adults with ulcerative colitis will receive their beginning (induction) doses with TREMFYA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. After completing the beginning (induction) doses, patients will receive TREMFYA as an injection under the skin (subcutaneous injection).
- Adults with Crohn's disease will receive their beginning (induction) doses with TREMFYA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider or as injections under the skin (subcutaneous injection). After completing the beginning (induction) doses, patients will receive TREMFYA as an injection under the skin (subcutaneous injection).

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:

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

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.

How should I store TREMFYA?

- Store TREMFYA in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Keep TREMFYA in the original carton to protect it from light until time of use.
- TREMFYA is not made with natural rubber latex.
- Do not freeze TREMFYA.
- Do not shake TREMFYA.

Keep TREMFYA and all medicines out of the reach of children.

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: Single-dose prefilled syringe, single-dose One-Press patient-controlled injector, single-dose prefilled pen for subcutaneous use (TREMFYA PEN): L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. Single-dose vial for intravenous infusion: EDTA disodium dihydrate, L-histidine, L-histidine monohydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA, U.S. License Number 1864
For patent information: www.janssenpatents.com

For more information, call 1-800-526-7736 or go to www.tremfya.com.

This Medication Guide had been approved by the U.S. Food and Drug Administration. Revised: 03/2025

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