TREMFYA® (guselkumab) What is the dosing schedule of TREMFYA[®] for Crohn's disease?

Dosage form and strengths¹

Intravenous infusion:

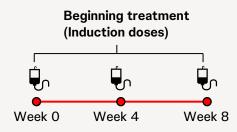
• 200 mg/20 mL (10 mg/mL) solution in a single-dose vial

Subcutaneous injection:

- 100 mg/mL in a single-dose One-Press patient-controlled injector
- 100 mg/mL in a single-dose prefilled syringe
- 100 mg/mL in a single-dose prefilled pen (TREMFYA PEN)
- 200 mg/2 mL in a single-dose prefilled pen (TREMFYA PEN)
- 200 mg/2 mL (100 mg/mL) in a single-dose prefilled syringe

Recommended dosage schedule¹

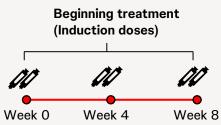
- The beginning (induction) doses of TREMFYA from the following 2 options: **Option 1:**
 - Through a vein in the arm (intravenous infusion)
 - In a healthcare facility by a healthcare provider



The recommended induction dosage of TREMFYA is 200 mg given by intravenous infusion over at least 1 hour at Week 0, Week 4, and Week 8.

Option 2:

As an injection under the skin (subcutaneous injection)

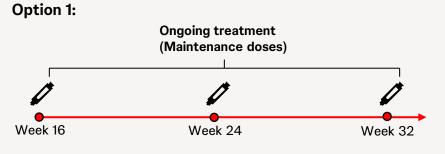


The recommended induction dosage of TREMFYA is 400 mg (given as two TREMFYA 200 mg injections one right after the other) at Week 0, Week 4, and Week 8.

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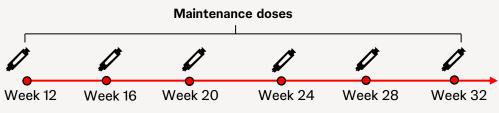
After completing the beginning (induction) doses:

- Patients will receive TREMFYA as an **injection under the skin** (subcutaneous injection) from the following 2 options:
- Your healthcare provider will determine the best treatment option for you to achieve desired results.



TREMFYA 100 mg given as a subcutaneous injection at Week 16, and then every 8 weeks.

Option 2:



TREMFYA 200 mg given as a subcutaneous injection at Week 12, and then every 4 weeks.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, **you should receive training** on the right way to prepare and inject TREMFYA before attempting to inject.

Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION, MEDICATION GUIDE and the INSTRUCTIONS FOR USE for TREMFYA®.¹ 1. TREMFYA (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; <u>https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf</u>.