Tremfya® (guselkumab)

For your adult patients with moderately to severely active
Crohn's disease or moderately to severely active **ulcerative colitis (UC)**

A GUIDE TO TREMFYA® DOSING

TREMFYA® is the **FIRST AND ONLY** IL-23i approved for Crohn's disease and UC to offer both **SC and IV induction**[1-3*]

Recommended dosage for Crohn's disease and UC: 400-mg SC injection or 200-mg IV infusion at Weeks 0, 4, and 8 followed by 100-mg SC injection q8w or 200-mg SC injection q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.[1]

*"Only" based on approved selective IL-23 inhibitors for moderately to severely active Crohn's disease or UC as of September 2025. Compared to Skyrizi® (risankizumab-rzaa) and Omvoh® (mirikizumab-mrkz) induction dosing. Skyrizi® and Omvoh® are not available as SC injection for induction therapy in Crohn's disease or UC.[1-3]

IL-23i=interleukin-23 inhibitor; IV=intravenous; q4w=every 4 weeks; q8w=every 8 weeks; SC=subcutaneous.

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, may occur. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis (TB) before treating with TREMFYA®. Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. Drug-induced liver injury has been reported. For the treatment of Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin levels at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in patients treated with TREMFYA®. Please see related and other Important Safety Information on page 6.

Please see full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

For adults with moderately to severely active

CROHN'S DISEASE

For adults with moderately to severely active

ULCERATIVE COLITIS

Tremfya® (guselkumab)

INDUCTION DOSING

Not actual size.

3 SC TREMFYA® PEN Induction Packs[1*]

400 mg by SC injection (given as two consecutive injections of 200 mg each) at Weeks 0, 4, and 8.

Week 0 — Week 4 — Week 8

Also available in prefilled syringe (200 mg/2 mL).

OR

Not actual size.

3 IV infusions (200 mg)[1†]

200 mg IV infusion administered over at least 1 hour at Weeks 0, 4, and 8.

Week 0 — Week 4 — Week 8

Pretreatment Evaluations: Evaluate for tuberculosis (TB) infection, evaluate liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines.[1]

Monitor: For signs and symptoms of active TB during and after treatment with TREMFYA®; liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management.[1]

TREMFYA® is intended for use under the guidance and supervision of a healthcare professional. After proper training in subcutaneous injection technique, adults may self-inject.[1]

MAINTENANCE DOSING

Not actual size.

TREMFYA® PEN (200 mg)[1‡]

200 mg administered by SC injection at Week 12, and every 4 weeks thereafter.

Week 12 — Week 16 — Week 20 — Week 24

Also available in prefilled syringe (200 mg/2 mL).

OR

Not actual size.

TREMFYA® PEN (100 mg)[1§]

100 mg administered by SC injection at Week 16, and every 8 weeks thereafter.

Week 16 — Week 24 — Week 32 — Week 40

Also available in One-Press patient-controlled injector or prefilled syringe (100 mg/mL).

Use the lowest effective recommended dosage to maintain therapeutic response.[1]

See page 4 for a complete list of NDC codes.

See device **demonstration videos.** ›

*Induction Pack: Carton containing two 200 mg/2 mL single-dose prefilled pens (400 mg/4 mL total) (TREMFYA® PEN).
†200 mg/20 mL (10 mg/mL) solution in a single-dose vial.
‡200 mg/2 mL in a single-dose prefilled pen.
§100 mg/mL in a single-dose prefilled pen.

IL-23i=interleukin-23 inhibitor; IV=intravenous; SC=subcutaneous; UC=ulcerative colitis.

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For Crohn's disease or ulcerative colitis:

WRITE TWO PRESCRIPTIONS

Tremfya® (guselkumab)

With SC induction, as little as 1 prior authorization may be required*

PRESCRIPTION #1

SC INDUCTION DOSING

Patient Name: _____

Date: _____

Prescription:

TREMFYA® (guselkumab)

1 x PEN **INDUCTION PACK**
(two 200-mg SUBQ pens)

SIG: 400 mg SUBQ
at Weeks 0, 4, and 8

2 refills

(NDC: 57894-651-04)

Signature: _____

OR

IV INDUCTION DOSING

Patient Name: _____

Date: _____

Prescription:

TREMFYA® (guselkumab)

200 mg IV

SIG: 200 mg/20 mL (10 mg/mL)
at Weeks 0, 4, and 8

No refills

(NDC: 57894-650-02)

Signature: _____

PRESCRIPTION #2

SC MAINTENANCE DOSING

Patient Name: _____

Date: _____

Prescription:

TREMFYA® (guselkumab)

200 mg SUBQ

SIG: 200 mg SUBQ
at Week 12, then q4w

Refills x 10

NDC: 57894-651-02
(TREMFYA® PEN)

NDC: 57894-651-22
(prefilled syringe)

Signature: _____

OR

SC MAINTENANCE DOSING

Patient Name: _____

Date: _____

Prescription:

TREMFYA® (guselkumab)

100 mg SUBQ

SIG: 100 mg SUBQ
at Week 16, then q8w

Refills x 5

NDC: 57894-640-06
(TREMFYA® PEN)

NDC: 57894-640-11
(One-Press)

NDC: 57894-640-01
(prefilled syringe)

Signature: _____

*Individual patient coverage may vary.
IV=intravenous; q4w=every 4 weeks; q8w=every 8 weeks; SC/SUBQ=subcutaneous.

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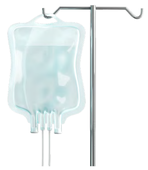
NDC CODES FOR TREMFYA®

Tremfya® (guselkumab)

TREMFYA® PEN Induction Pack (2 x 200 mg)

NDC 57894-**651**-04



Single-dose vial for IV infusion (200 mg)

NDC 57894-**650**-02

TREMFYA® PEN (200 mg)

NDC 57894-**651**-02

Prefilled Syringe (200 mg)

NDC 57894-**651**-22

TREMFYA® PEN (100 mg)

NDC 57894-**640**-06

Prefilled Syringe (100 mg)

NDC 57894-**640**-01

One-Press patient-controlled injector (100 mg)

NDC 57894-**640**-11

Product images not actual size.

IV=intravenous; NDC=National Drug Code.

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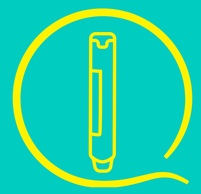
Tremfya withMe | Tremfya® (guselkumab)

Once a decision has been made to prescribe TREMFYA®

TREMFYA withMe can help support eligible commercial patients to start and stay on TREMFYA®*



Eligible patients can receive their first subcutaneous trial dose through TREMFYA withMe in as fast as 1 day†

Learn more about TREMFYA® Access and Support

The patient support and resources provided by TREMFYA withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TREMFYA®.

*Individual patient coverage may vary.
†See program requirements for the TREMFYA withMe Trial Offer at TREMFYAwithMeTrial.com.

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Tremfya® (guselkumab)

INDICATIONS

TREMFYA® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

TREMFYA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection. Initiate treatment of latent TB prior to administering TREMFYA®. Consider anti-TB therapy prior to initiating TREMFYA® in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor all patients for signs and symptoms of active TB during and after TREMFYA® treatment.

Hepatotoxicity

A serious adverse reaction of drug-induced liver injury was reported in a clinical trial subject with Crohn's disease following three doses of a higher than recommended induction regimen.

In patients with Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management.

Consider other treatment options in patients with evidence of acute liver disease or cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Prior to initiating TREMFYA®, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common adverse reactions associated with TREMFYA® include: ulcerative colitis adverse reactions (≥3%): injection site reactions, arthralgia, upper respiratory tract infections, headache, gastroenteritis, fatigue, pyrexia, and rash. Crohn's disease adverse reactions (≥3%): respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

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Dosage Forms and Strengths: TREMFYA® is available as 100 mg/mL and 200 mg/2 mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single-dose vial for intravenous infusion.

cp-510996v2

References: 1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Skyrizi® [Prescribing Information]. North Chicago, IL: AbbVie Inc. **3.** Omvoh® [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company.

Johnson&Johnson