Lexicomp®

(For additional information see "Guselkumab: Patient drug information")

For abbreviations and symbols that may be used in Lexicomp (show table)

Brand Names: US

Tremfya

Brand Names: Canada

Tremfya

Pharmacologic Category

Antipsoriatic Agent; Interleukin-23 Inhibitor; Monoclonal Antibody

Dosing: Adult

Plaque psoriasis: SubQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter.

Psoriatic arthritis: SubQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter; may administer alone or in combination with conventional disease-modifying antirheumatic drugs (eg, methotrexate).

Dosing: Renal Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling (has not been studied).

Dosing: Hepatic Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling (has not been studied).

Dosing: Geriatric

Refer to adult dosing.

Dosage Forms: US

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution Pen-injector, Subcutaneous [preservative free]:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Solution Prefilled Syringe, Subcutaneous [preservative free]:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Generic Equivalent Available: US

No

Dosage Forms: Canada

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution Pen-injector, Subcutaneous:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Solution Prefilled Syringe, Subcutaneous:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

Medication Guide and/or Vaccine Information Statement (VIS)

An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication;

Tremfya: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761061s009lbl.

pdf#page=15

Administration: Adult

SubQ: Administer SubQ into front of thighs, lower abdomen (except for 2 inches around navel), or back of upper arms; do not inject into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis.

Use: Labeled Indications

Plaque psoriasis: Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic arthritis: Treatment of active psoriatic arthritis in adults.

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified.

>10%:

Infection: Infection (23%)

Respiratory: Upper respiratory tract infection (14%)

1% to 10%:

Dermatologic: Tinea (1%)

Gastrointestinal: Diarrhea (2%), gastroenteritis (1%)

Hematologic & oncologic: Decreased neutrophils (≤2%; transient)

Hepatic: Increased liver enzymes (3%)

Immunologic: Antibody development (6% to 9%; neutralizing antibodies: 6% to 7%; efficacy of guselkumab may be affected)

Infection: Herpes simplex infection (1%)

Local: Injection site reaction (5%)

Nervous system: Headache (5%)

Neuromuscular & skeletal: Arthralgia (3%)

Respiratory: Bronchitis (2% to 3%)

<1%:

Dermatologic: Urticaria

Infection: Candidiasis

Nervous system: Migraine

Postmarketing:

Dermatologic: Skin rash

Hypersensitivity: Anaphylaxis, hypersensitivity reaction, severe hypersensitivity reaction

Contraindications

Serious hypersensitivity to guselkumab or any component of the formulation.

Warnings/Precautions

Concerns related to adverse effects:

• Antibody formation: Formation of neutralizing anti-drug antibodies may occur with biologic tumor necrosis factor inhibitors but has not been associated with loss of efficacy for guselkumab (AAD/NPF [Menter 2019]).

• Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur; may require hospitalization. Discontinue use and initiate appropriate therapy if serious hypersensitivity reactions occur.

• Infections: Guselkumab may increase the risk of infections; upper

respiratory tract infections, gastroenteritis, tinea infections, and herpes simplex infections have occurred more frequently. Consider the risks versus benefits prior to treatment initiation in patients with a history of chronic or recurrent infection; treatment should not be initiated in patients with clinically important active infections until it is resolved or treated. Monitor for infections; patients should seek medical attention for signs/symptoms of a clinically important infection (acute or chronic). If a serious infection develops or is unresponsive to appropriate therapy for the infection, monitor closely and discontinue guselkumab until the infection resolves.

• Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy. Do not administer to patients with an active TB infection. Treatment for latent TB should be administered prior to administering guselkumab. Consider anti-TB therapy prior to treatment initiation in patients with a history of latent or active TB in whom an adequate course of TB treatment cannot be confirmed. Monitor closely for signs/symptoms of active TB during and after guselkumab treatment.

Other warnings/precautions:

• Immunizations: Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently; there are no data available concerning secondary transmission of infection by live vaccines in patients receiving therapy.

Metabolism/Transport Effects

None known.

Drug Interactions

(For additional information: Launch drug interactions program) Lexicomp®

Baricitinib: Immunosuppressants may enhance the immunosuppressive effect of Baricitinib. Management: Use of baricitinib in combination with potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

Concurrent use with antirheumatic doses of methotrexate or nonbiologic disease modifying antirheumatic drugs (DMARDs) is permitted. *Risk D: Consider therapy modification*

BCG (Intravesical): Immunosuppressants may diminish the therapeutic effect of BCG (Intravesical). *Risk X: Avoid combination*

Belimumab: May enhance the immunosuppressive effect of Biologic Anti-Psoriasis Agents. *Risk X: Avoid combination*

Brincidofovir: Immunosuppressants may diminish the therapeutic effect of Brincidofovir. *Risk C: Monitor therapy*

Cladribine: May enhance the immunosuppressive effect of Immunosuppressants. *Risk X: Avoid combination*

Coccidioides immitis Skin Test: Immunosuppressants may diminish the diagnostic effect of Coccidioides immitis Skin Test. *Risk C: Monitor therapy*

COVID-19 Vaccine (Adenovirus Vector): Immunosuppressants may diminish the therapeutic effect of COVID-19 Vaccine (Adenovirus Vector). *Risk C: Monitor therapy*

COVID-19 Vaccine (Inactivated Virus): Immunosuppressants may diminish the therapeutic effect of COVID-19 Vaccine (Inactivated Virus). *Risk C: Monitor therapy*

COVID-19 Vaccine (mRNA): Immunosuppressants may diminish the therapeutic effect of COVID-19 Vaccine (mRNA). *Risk C: Monitor therapy*

Denosumab: May enhance the adverse/toxic effect of Immunosuppressants. Specifically, the risk for serious infections may be increased. *Risk C: Monitor therapy*

Echinacea: May diminish the therapeutic effect of Immunosuppressants. Management: Consider avoiding Echinacea in patients receiving therapeutic immunosuppressants. If coadministered, monitor for reduced efficacy of the immunosuppressant during concomitant use. *Risk D: Consider therapy*

modification

Fingolimod: Immunosuppressants may enhance the immunosuppressive effect of Fingolimod. Management: Avoid the concomitant use of fingolimod and other immunosuppressants when possible. If combined, monitor patients closely for additive immunosuppressant effects (eg, infections). *Risk D: Consider therapy modification*

Inebilizumab: May enhance the immunosuppressive effect of Immunosuppressants. *Risk C: Monitor therapy*

InFLIXimab: May enhance the immunosuppressive effect of Biologic Anti-Psoriasis Agents. *Risk X: Avoid combination*

Leflunomide: Immunosuppressants may enhance the adverse/toxic effect of Leflunomide. Specifically, the risk for hematologic toxicity such as pancytopenia, agranulocytosis, and/or thrombocytopenia may be increased. Management: Consider not using a leflunomide loading dose in patients receiving other immunosuppressants. Patients receiving both leflunomide and another immunosuppressant should be monitored for bone marrow suppression at least monthly. *Risk D: Consider therapy modification*

Measles, Mumps, and Rubella Virus Vaccine: Immunosuppressants may enhance the adverse/toxic effect of Measles, Mumps, and Rubella Virus Vaccine. *Risk X: Avoid combination*

Measles, Mumps, Rubella, and Varicella Virus Vaccine: Immunosuppressants may enhance the adverse/toxic effect of Measles, Mumps, Rubella, and Varicella Virus Vaccine. *Risk X: Avoid combination*

Natalizumab: Immunosuppressants may enhance the adverse/toxic effect of Natalizumab. Specifically, the risk of concurrent infection may be increased. *Risk X: Avoid combination*

Ocrelizumab: May enhance the immunosuppressive effect of Immunosuppressants. *Risk C: Monitor therapy*

Ofatumumab: May enhance the immunosuppressive effect of Immunosuppressants. *Risk C: Monitor therapy*

Ozanimod: Immunosuppressants may enhance the immunosuppressive effect of Ozanimod. *Risk C: Monitor therapy*

Pidotimod: Immunosuppressants may diminish the therapeutic effect of Pidotimod. *Risk C: Monitor therapy*

Pimecrolimus: May enhance the adverse/toxic effect of Immunosuppressants. *Risk X: Avoid combination*

Polymethylmethacrylate: Immunosuppressants may enhance the potential for allergic or hypersensitivity reactions to Polymethylmethacrylate. The clearance of the bovine collagen component may also be accelerated. *Risk C: Monitor therapy*

Ponesimod: Immunosuppressants may enhance the immunosuppressive effect of Ponesimod. *Risk C: Monitor therapy*

Rabies Vaccine: Immunosuppressants may diminish the therapeutic effect of Rabies Vaccine. Management: If possible, complete rabies vaccination at least 2 weeks prior to initiation of immunosuppressant therapy. If rabies post-exposure vaccine series is required while receiving immunosuppressant therapy, administer a 5th dose of rabies vaccine. *Risk D: Consider therapy modification*

Roflumilast: May enhance the immunosuppressive effect of Immunosuppressants. Management: Consider avoiding concomitant use of roflumilast and immunosuppressants as recommended by the Canadian product monograph. Inhaled or short-term corticosteroids are unlikely to be problematic. *Risk D: Consider therapy modification*

Siponimod: Immunosuppressants may enhance the immunosuppressive effect of Siponimod. *Risk C: Monitor therapy*

Sipuleucel-T: Immunosuppressants may diminish the therapeutic effect of Sipuleucel-T. Management: Evaluate patients to see if it is medically appropriate

to reduce or discontinue therapy with immunosuppressants prior to initiating sipuleucel-T therapy. *Risk D: Consider therapy modification*

Tacrolimus (Topical): May enhance the adverse/toxic effect of Immunosuppressants. *Risk X: Avoid combination*

Talimogene Laherparepvec: Immunosuppressants may enhance the adverse/toxic effect of Talimogene Laherparepvec. Specifically, the risk for disseminated herpetic infection may be increased. *Risk X: Avoid combination*

Tertomotide: Immunosuppressants may diminish the therapeutic effect of Tertomotide. *Risk C: Monitor therapy*

Tofacitinib: Immunosuppressants may enhance the immunosuppressive effect of Tofacitinib. Management: Concurrent use with antirheumatic doses of methotrexate or nonbiologic disease modifying antirheumatic drugs (DMARDs) is permitted, and this warning seems particularly focused on more potent immunosuppressants. *Risk D: Consider therapy modification*

Upadacitinib: Immunosuppressants may enhance the immunosuppressive effect of Upadacitinib. Management: Concomitant use of upadacitinib with potent immunosuppressants is not recommended. *Risk X: Avoid combination*

Vaccines (Inactivated): Immunosuppressants may diminish the therapeutic effect of Vaccines (Inactivated). Management: Complete all age-appropriate vaccinations at least 2 weeks prior to starting an immunosuppressant. If vaccinated less than 2 weeks before starting or during immunosuppressant therapy, revaccinate at least 3 months after immunosuppressant discontinuation. *Risk D: Consider therapy modification*

Vaccines (Live): Guselkumab may enhance the adverse/toxic effect of Vaccines (Live). *Risk X: Avoid combination*

Varicella Virus Vaccine: Immunosuppressants may enhance the adverse/toxic effect of Varicella Virus Vaccine. *Risk X: Avoid combination*

Pregnancy Considerations

Guselkumab is a humanized monoclonal antibody (IgG_1). Placental transfer of human IgG is dependent upon the IgG subclass, maternal serum concentrations, birth weight, and gestational age, generally increasing as pregnancy progresses. The lowest exposure would be expected during the period of organogenesis (Palmeira 2012; Pentsuk 2009).

Agents other than guselkumab are currently recommended for the treatment of psoriasis in pregnancy (AAD/NPF [Menter 2019]; Yeung 2020).

Data collection to monitor pregnancy and infant outcomes following exposure to guselkumab is ongoing. Patients exposed to guselkumab during pregnancy are encouraged to enroll themselves in the pregnancy registry (1-877-311-8972).

Breast-Feeding Considerations

> It is not known if guselkumab is present in breast milk.
>
> However, guselkumab is a monoclonal IgG antibody; human IgG is known to be present in human milk. According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother.

Monitoring Parameters

CBC with differential (baseline); complete metabolic panel (baseline); tuberculosis (TB) screening prior to initiating and during therapy (chest X-ray if TB positive); hepatitis B virus (HBV)/hepatitis C virus screening prior to initiating (all patients), HBV carriers (during and for several months following therapy); HIV screening in high-risk patients (baseline) (AAD/NPF [Menter 2019]).

Mechanism of Action

Human IgG1 monoclonal antibody selectively binds with IL-23, thereby reducing

serum levels of IL-17A, IL-17F, and IL-22. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.

Pharmacodynamics and Pharmacokinetics

Onset of action: Psoriasis: Response best determined after 12 weeks (AAD/NPF [Menter 2019]).

Distribution: V_d: 13.5 L.

Metabolism: Degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG.

Bioavailability: SubQ: ~49%.

Half-life elimination: 15 to 18 days.

Time to peak: 5.5 days.

Pricing: US

Solution Pen-injector (Tremfya Subcutaneous)

100 mg/mL (per mL): $14,326.04

Solution Prefilled Syringe (Tremfya Subcutaneous)

100 mg/mL (per mL): $14,326.04

its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

Brand Names: International

Tremfya (AU, BE, CH, DE, DK, EE, ES, FI, GB, IL, LB, LT, LV, NL, PL, RO, SE, SK)

For country abbreviations used in Lexicomp (show table)

REFERENCES

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4. *Tremfya (guselkumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; July 2020.*

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6. *Yeung J, Gooderham MJ, Grewal P, et al. Management of plaque psoriasis with biologic therapies in women of child-bearing potential consensus paper. J Cutan Med Surg. 2020;24(1_suppl):3S-14S. doi:10.1177/1203475420928376 [PubMed 32500730]*

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