Vilobelimab (Lexi-Drugs)

**Pronunciation**

(VIL oh BEL i mab)

**Pharmacologic Category**

Antiviral Agent; Monoclonal Antibody

**Dosing: Adult**

COVID-19, treatment

**COVID-19, treatment (off-label use):**

*IV*: 800 mg once on day 1 (within 48 hours of intubation), followed by 800 mg once daily on days 2, 4, 8, 15, and 22, as long as the patient remains hospitalized (even if discharged from the ICU) (Ref).

**Dosing: Older Adult**

Refer to adult dosing.

**Dosing: Altered Kidney Function: Adult**

There are no dosage adjustments provided (Ref).

**Dosing: Hepatic Impairment: Adult**

There are no dosage adjustments provided (Ref).

**Use: Labeled Indications**

See “Use: Off-Label.”

**Use: Off-Label: Adult**

COVID-19, treatmentLevel of Evidence [A]

Data from a randomized, double-blind, placebo-controlled multicenter trial support the use of vilobelimab, in addition to standard of care, in the treatment of COVID-19 in patients receiving invasive mechanical ventilation (Ref).

Under the EUA issued by the FDA, vilobelimab may be used for treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (Ref).

**Clinical Practice Guidelines**

COVID-19:
Administration: IV

If diluted solution is refrigerated prior to administration, allow to come to room temperature prior to administration. Administer as an IV infusion in a dedicated IV line over 30 to 60 minutes (Ref).

Administration: Injectable Detail

pH: 6.6 to 7.3 (vial).

Storage/Stability

Store intact vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake. Diluted solution may be stored ≤4 hours at 20°C to 25°C (68°F to 77°F) or ≤24 hours refrigerated at 2°C to 8°C (36°F to 46°F) (FDA 2023).

Preparation for Administration: Adult

Withdraw 80 mL from a 250 mL NS IV infusion bag and discard; withdraw 80 mL of vilobelimab from the vials, slowly add to the infusion bag, and mix by gently inverting to avoid foaming (final concentration: 3.2 mg/mL) (Ref).

IV Compatibility

See Trissel's IV Compatibility Database

Open Trissel's IV Compatibility

Patient Counseling Points

What is this drug used for?

• It is used in certain people to treat COVID-19.

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Constipation

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal

• Urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain

• High blood pressure like very bad headache or dizziness, passing out, or change in eyesight
Feeling confused

Any unexplained bruising or bleeding

Fast or abnormal heartbeat

Blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing

Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine's uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.

Medication Safety Issues

Sound-alike/look-alike issues:

Vilobelimab may be confused with belimumab, vilazodone, or viloxazine.

Prescribing and Access Restrictions

Vilobelimab is not commercially available; it is available as part of ongoing clinical trials and through an emergency use authorization (EUA) from the FDA.

As part of the EUA, fact sheets pertaining to emergency use of vilobelimab are required to be available for health care providers and patients/caregivers, and certain mandatory requirements for vilobelimab administration under the EUA must be met as outlined in the FDA EUA letter; the fact sheets and EUA letter may be accessed at https://www.gohibic.com. Additionally, health care providers must track and report all medication errors and serious adverse events potentially associated with vilobelimab use by submitting FDA Form 3500 (health professional, available at: https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500) online (www.fda.gov/medwatch/report.htm), by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-0178), or by calling 1-800-FDA-1088 to request a reporting form; a copy of all
forms should also be provided to InflaRx GmbH (phone: 1-888-254-0602; fax: 1-866-728-2630; email: pvusa@inflarx.de).

Contraindications

There are no contraindications listed in the manufacturer's labeling.

Warnings/Precautions

Concerns related to adverse effects:

- Hypersensitivity: Serious hypersensitivity reactions have been observed with administration of vilobelimab (FDA 2023).

- Infection: Serious infections due to bacterial, fungal, and viral pathogens have been reported in patients with COVID-19 receiving vilobelimab. Consider the risk/benefits of treatment with vilobelimab in patients with COVID-19 and other concurrent infections (FDA 2023).

Dosage form specific issues:

- Sodium: Some products may contain sodium.

Pregnancy Considerations

Vilobelimab is a chimeric human/mouse immunoglobulin (IgG4) antibody. Human IgG crosses the placenta. Fetal exposure is dependent upon the IgG subclass, maternal serum concentrations, placental integrity, newborn birth weight, and GA, generally increasing as pregnancy progresses. The lowest exposure would be expected during the period of organogenesis and the highest during the third trimester (Clements 2020; Palmeira 2012; Pentsuk 2009).

Breastfeeding Considerations

It is not known if vilobelimab is present in breast milk.

Vilobelimab is a chimeric human/mouse immunoglobulin (IgG4) antibody. Human IgG is present in breast milk; concentrations are dependent upon IgG subclass and postpartum age (Anderson 2021).

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 the benefits of treatment to the mother.

Adverse Reactions

The following adverse drug reactions and incidences are derived from the FDA issued emergency use authorization (EUA), unless otherwise specified. Refer to EUA for information regarding reporting adverse reactions (FDA 2023).

>10%:

Cardiovascular: Pulmonary embolism (11%)

Infection: Sepsis (22%), serious infection (33%)
Nervous system: Delirium (13%)
Respiratory: Pneumonia (31%)
1% to 10%:
Cardiovascular: Deep vein thrombosis (6%), hypertension (9%), supraventricular tachycardia (4%)
Dermatologic: Skin rash (3%)
Gastrointestinal: Constipation (3%)
Genitourinary: Urinary tract infection (5%)
Hematologic & oncologic: Thrombocytopenia (5%)
Hepatic: Increased liver enzymes (5%)
Infection: Herpes simplex infection (6%), infection due to enterococcus (6%), septic shock (9%)
Respiratory: Hypoxia (5%), pneumothorax (8%), pulmonary aspergillosis (6%), pulmonary complications (pneumomediastinum: 5%), respiratory tract infection (4%)
Frequency not defined:
Cardiovascular: Hemodynamic deterioration
Dermatologic: Eczema
Hypersensitivity: Hypersensitivity reaction
Miscellaneous: Multi-organ failure

Metabolism/Transport Effects
None known.

Drug Interactions Open Interactions

Note: Interacting drugs may not be individually listed below if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the Lexicomp drug interactions program by clicking on the "Open Interactions" button above.

Abrocitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). Risk X: Avoid combination

Antithymocyte Globulin (Equine): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Antithymocyte Globulin (Equine). Specifically, these effects may be unmasked if the dose of immunosuppressive therapy is reduced. Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Antithymocyte Globulin (Equine). Specifically, infections may occur with greater severity and/or atypical presentations. Risk C: Monitor therapy
Baricitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Baricitinib. *Risk X: Avoid combination*

Brincidofovir: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Brincidofovir. *Risk C: Monitor therapy*

Brivudine: May enhance the adverse/toxic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Cladribine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Cladribine. *Risk X: Avoid combination*

Coccidioides immitis Skin Test: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the diagnostic effect of Coccidioides immitis Skin Test. Management: Consider discontinuing therapeutic immunosuppressants several weeks prior to coccidioides immitis skin antigen testing to increase the likelihood of accurate diagnostic results. *Risk D: Consider therapy modification*

Denosumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Denosumab. Management: Consider the risk of serious infections versus the potential benefits of coadministration of denosumab and immunosuppressants. If combined, monitor for signs/symptoms of serious infections. *Risk D: Consider therapy modification*

Deucravacitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Efgartigimod Alfa: May diminish the therapeutic effect of Fc Receptor-Binding Agents. *Risk C: Monitor therapy*

Filgotinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Inebilizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Inebilizumab. *Risk C: Monitor therapy*

Leflunomide: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Leflunomide. Management: Increase the frequency of chronic monitoring of platelet, white blood cell count, and hemoglobin or hematocrit to monthly, instead of every 6 to 8 weeks, if leflunomide is coadministered with immunosuppressive agents. *Risk D: Consider therapy modification*

Nadofaragene Firadenovec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Nadofaragene Firadenovec. Specifically, the risk of disseminated adenovirus infection may be increased. *Risk X: Avoid combination*

Natalizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Natalizumab. *Risk X: Avoid combination*

Ocrelizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ocrelizumab. *Risk C: Monitor therapy*
Ofatumumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ofatumumab. **Risk C: Monitor therapy**

Pidotimod: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Pidotimod. **Risk C: Monitor therapy**

Pimecrolimus: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Pimecrolimus. **Risk X: Avoid combination**

Polymethylmethacrylate: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the potential for allergic or hypersensitivity reactions to Polymethylmethacrylate. Management: Use caution when considering use of bovine collagen-containing implants such as the polymethylmethacrylate-based Bellafill brand implant in patients who are receiving immunosuppressants. Consider use of additional skin tests prior to administration. **Risk D: Consider therapy modification**

Ruxolitinib (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ruxolitinib (Topical). **Risk X: Avoid combination**

Sipuleucel-T: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Sipuleucel-T. Management: Consider reducing the dose or discontinuing the use of immunosuppressants prior to initiating sipuleucel-T therapy. **Risk D: Consider therapy modification**

Sphingosine 1-Phosphate (S1P) Receptor Modulator: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). **Risk C: Monitor therapy**

Tacrolimus (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tacrolimus (Topical). **Risk X: Avoid combination**

Talimogene Laherparepvec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Talimogene Laherparepvec. Specifically, the risk of infection from the live, attenuated herpes simplex virus contained in talimogene laherparepvec may be increased. **Risk X: Avoid combination**

Tertomotide: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Tertomotide. **Risk X: Avoid combination**

Tofacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tofacitinib. Management: Coadministration of tofacitinib with potent immunosuppressants is not recommended. Use with non-biologic disease-modifying antirheumatic drugs (DMARDs) was permitted in psoriatic arthritis clinical trials. **Risk X: Avoid combination**

Ublituximab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ublituximab. **Risk C: Monitor therapy**

Upadacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Upadacitinib. **Risk X: Avoid combination**

**Monitoring Parameters**

Signs and symptoms of new infection during and after treatment.
**Product Availability**

Investigational agent; approved for emergency use authorization by the FDA in April 2023.

**Mechanism of Action**

Vilobelimab is a chimeric human/mouse monoclonal IgG4-kappa antibody that binds to C5a and blocks its interaction with the C5a receptor. C5a is part of the complement system and is activated as part of the innate immune response, initiating an inflammatory cascade that includes increased vascular permeability, coagulation, proinflammatory cytokine release, and recruitment and activation of neutrophils and other myeloid cells (FDA 2023).

**Pharmacokinetics (Adult Data Unless Noted)**

Half-life elimination: 95 hours.

**Dental: Local Anesthetic/Vasoconstrictor Precautions**

Use vasoconstrictor with caution in patients taking vilobelimab. The drug is associated with occurrence of hypertension and tachycardia.

**Dental: Effects on Dental Treatment**

No significant effects or complications reported.

**Dental: Effects on Bleeding**

No information available to require special precautions.

**Index Terms**

Coronavirus; COVID-19; Gohibic; IFX-1

**FDA Approval Date**

April 04, 2023

**References**


