Product Focus

HEALTHDIRECT PHARMACY SERVICES

Evusheld (tixagevimab-cilgavimab)

July 2022

Evusheld (tixagevimab-cilgavimab) - EMERGENCY USE AUTHORIZATION

Tixagevimab-cilgavimab is authorized under the EUA to be used for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg). It is only authorized for those who aren't currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**:

- who are moderately to severely immunocompromised due to a medical condition or who have received immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination; or
- for whom vaccination with any available approved or authorized COVID-19 vaccine is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Description:

Tixagevimab, a SARS-CoV-2 spike protein-directed attachment inhibitor, is a human immunoglobulin G1 (IgG1κ) monoclonal antibody produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology.

Dosage Forms:

Injection:
Each EvuSheld carton contains 2 vials: one of each antibody.

- tixagevimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial.
- cilgavimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial.

Dosage and Administration: *The dosage of EVUSHELD for emergency use:*

- Initial dosing: The initial dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular (IM) injections.
- Dosing for Individuals Who Initially Received 150 mg of Tixagevimab and 150 mg of Cilgavimab: Individuals who have already received the previously authorized initial dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional EVUSHELD dose as soon as possible, with the dose based on the following criteria:
  - If the patient received their initial dose ≤ 3 months ago, the patient should receive a dose of 150 mg of tixagevimab and 150 mg of cilgavimab
  - If the patient received their initial dose > 3 months ago, the patient should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab.
- Repeat dosing: The repeat dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 300 mg of tixagevimab and 300 mg of cilgavimab administered every 6 months. Repeat dosing should be timed from the date of the most recent EVUSHELD dose. **For individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.**

***Product is preservative-free and therefore, once the syringes are prepared with the solution, they should be administered immediately. If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration must not exceed 4 hours:

— in a refrigerator at 2°C to 8°C (36°F to 46°F), or
— at room temperature up to 25°C (77°F).

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Warnings:

- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

Adverse Drug Reactions:

Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough.

Renal And Hepatic Function:

Renal impairment is not expected to impact the PK of tixagevimab and cilgavimab, since monoclonal antibodies with molecular weight >69 kDa are known not to undergo renal elimination. No specific studies have been conducted to examine the effects of hepatic impairment on the PK of tixagevimab and cilgavimab.

Drug Interactions:

Drug-drug interaction studies have not been performed.

Storage and Handling:

Storage and Handling Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Discard any unused portion. **DO NOT FREEZE. DO NOT SHAKE**.

FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR EVUSHELD
https://www.fda.gov/media/154701/download

FDA's Frequently Asked Questions (FAQs): FOR EVUSHELD
https://www.fda.gov/media/154703/download