AstraZeneca

IMPORTANT PRESCRIBING INFORMATION

Subject: Updated EVUSHELD Emergency Use Authorization (EUA) Dosage Recommendations for Patients Who Received an Initial Dose of 150 mg tixagevimab and 150 mg cilgavimab

Dear Healthcare Provider:

The EVUSHELD (tixagevimab co-packaged with cilgavimab) dosage recommendations under the Emergency Use Authorization (EUA) have been updated to provide additional guidance for patients who received only an initial dose of 150 mg tixagevimab and 150 mg cilgavimab. There are no changes to the authorized dose for patients who received an initial dose of 300 mg tixagevimab and 300 mg cilgavimab.

The revised authorized dosage regimen is as follows:

Individuals who received only 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, refer to Table 2 below.
- 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, refer to Table 1 below.

HEALTHCARE PROVIDER ACTION

Healthcare providers should refer to the most current EUA Fact Sheet (www.evusheld.com) for the most accurate information.

To minimize dose preparation and administration errors, it is critical that **all orders for EVUSHELD** specify the numeric dose of each monoclonal antibody within **EVUSHELD** as follows:

- 300 mg of tixagevimab and 300 mg of cilgavimab, or
- 150 mg of tixagevimab and 150 mg of cilgavimab

Each carton of **EVUSHELD** contains two vials (one vial of 150 mg/1.5 mL tixagevimab and one vial of 150 mg/1.5 mL cilgavimab). There are **differences in product preparation** based on the prescribed dosage as outlined in Table 1 and 2 below:

AstraZeneca

Table 1. Dosage of 300 mg of Tixagevimab and 300 mg of Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	**Antibody dose**	**Number of vials needed**	**Volume to withdraw from vials**
	tixagevimab 300 mg	2 vials	3 mL * **(1.5 ml from each vial into the same syringe)**
	cilgavimab 300 mg	2 vials	3 mL * **(1.5 ml from each vial into the same syringe)**

*Each carton of **EVUSHELD** contains one vial of tixagevimab 150 mg/1.5 mL and one vial of cilgavimab 150 mg/1.5 mL. The 300 mg of tixagevimab and 300 mg of cilgavimab doses are to be administered as separate, consecutive intramuscular injections. Withdraw the 3 mL of tixagevimab solution and 3 mL of cilgavimab solution into TWO separate syringes. Each vial has overfill to enable withdrawal of 1.5 ml from each vial. **Any leftover product should be discarded.**

Table 2. Dosage of 150 mg of Tixagevimab and 150 mg of Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	**Antibody dose**	**Number of vials needed**	**Volume to withdraw from vials**
	tixagevimab 150 mg	1 vial	1.5 mL*
	cilgavimab 150 mg	1 vial	1.5 mL*

* Each carton of EVUSHELD contains one vial of tixagevimab 150 mg/1.5 mL and one vial of cilgavimab 150 mg/1.5 mL. The 150 mg of tixagevimab and 150 mg of cilgavimab doses are to be administered as separate, consecutive intramuscular injections. Withdraw the 1.5 mL of tixagevimab solution and 1.5 mL of cilgavimab solution into TWO separate syringes. Each vial has overfill to enable withdrawal of 1.5 ml from each vial. **Any leftover product should be discarded.**

Administer the two components of EVUSHELD consecutively as intramuscular (IM) injections at different injection sites one after the other. The location of the intramuscular (IM) injections for the 300 mg of tixagevimab and 300 mg of cilgavimab dose should be limited to large muscles that can accommodate this volume (e.g., the gluteal muscles or anterolateral thigh muscles).

The Emergency Use Authorization Fact Sheet for Healthcare Providers is included

with this notice, available at www.evusheld.com or available by scanning the QR Code below:

Reporting Adverse Events

The prescribing healthcare provider and/or your designee must report all SERIOUS ADVERSE EVENTS and all MEDICATION ERRORS potentially related to **EVUSHELD** within 7 calendar days from the healthcare provider's awareness of the event (1) by submitting FDA Form 3500 online, (2) by downloading FDA Form 3500 and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form.

In addition, please fax a copy of all FDA MedWatch forms to AstraZeneca at 1-866-742-7984. Report adverse events by visiting https://contactazmedical.astrazeneca.com, or calling AstraZeneca at 1-800-236-9933.

Sincerely,

DocuSigned by:
Hugo Gomes da Silva
766934D57B9D4A1...

Hugo Gomes da Silva, MD

Vice President, Global Medical Affairs