

IMPORTANT PRESCRIBING INFORMATION

Subject: New Repeat Dosage Recommendations for Emergency Use Authorization (EUA) for EVUSHELD

Dear Healthcare Provider:

The EVUSHELD (tixagevimab co-packaged with cilgavimab) dosage recommendations under the Emergency Use Authorization (EUA) have been updated to provide guidance for repeat dosing. There are no changes to the authorized initial dose for patients (i.e., 300 mg tixagevimab and 300 mg cilgavimab).

The repeat dosage regimen is as follows:

<u>Repeat Dosing</u> (refer to the EUA Healthcare Provider Fact Sheet, Section 2.1) 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.

HEALTHCARE PROVIDER ACTION

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

The Emergency Use Authorization Fact Sheet for Healthcare Providers is included with this notice, available at <u>www.evusheld.com</u> or available by scanning the QR Code below:



Reporting Adverse Events and Medication Errors

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 <u>online at www.fda.gov/medwatch/report.htm</u>, (2) by <u>downloading</u> FDA Form 3500 at <u>https://www.fda.gov/media/76299/download</u> 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 <u>https://contactazmedical.astrazeneca.com</u>, or calling AstraZeneca at 1-800-236-9933.

Sincerely,

DocuSigned by: Raduele Berria Rachele Berria, MD PhD

Vice President and Medical Head

US BioPharmaceuticals

AstraZeneca