AstraZeneca

IMPORTANT PRESCRIBING INFORMATION

Subject: Addition of EVUSHELD Emergency Use Authorization (EUA) Warning and Precaution for Risk of Cross-Hypersensitivity with COVID-19 Vaccines

Dear Healthcare Provider:

The EVUSHELD™ (tixagevimab co-packaged with cilgavimab) Warnings and Precautions under the Emergency Use Authorization (EUA) have been updated to add a new statement related to Risk of Cross-Reactivity with COVID-19 Vaccines (see section 5.2 below).

5.2 Risk of Cross-Hypersensitivity with COVID-19 Vaccines (*new*)

EVUSHELD contains polysorbate 80, which is in some COVID-19 vaccines and is structurally similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. For individuals with a history of a severe hypersensitivity reaction to a COVID-19 vaccine, consider consultation with an allergist-immunologist prior to EVUSHELD administration.

Administration of EVUSHELD should be done under the supervision of a healthcare provider with appropriate medical support to manage severe hypersensitivity reactions. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur while taking EVUSHELD, immediately discontinue administration and initiate appropriate medications and/or supportive care. Clinically monitor individuals after injections and observe for at least 1 hour.

HEALTHCARE PROVIDER ACTION

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

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:
Rachele Berria
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Rachele Berria Friend, MD

Vice President, US Medical