AstraZeneca

IMPORTANT PRESCRIBING INFORMATION

Subject: EVUSHELD Emergency Use Authorization (EUA) Update

Dear Healthcare Provider:

Given the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to EVUSHELD, EVUSHELD is not currently authorized in any U.S. regions. EVUSHELD is authorized for use only when the combined estimated frequency of non-susceptible variants nationally is less than or equal to 90%, based on available information including variant susceptibility to EVUSHELD and national variant frequencies. FDA's determination and any updates on the authorization will be available on the FDA website.

HEALTHCARE PROVIDER ACTION

Patients who have received EVUSHELD should be reminded to seek timely medical attention if they experience symptoms of COVID-19 and start treatment when appropriate. United States Government recommends all EVUSHELD product be retained in the event that SARS-CoV-2 variants susceptible to EVUSHELD, including those that are currently circulating at lower prevalence, become more prevalent in the future.

The following cartons with the following lot numbers of EVUSHELD have had their expiration dates extended by 12 months:

AZ210059, AZ210062, AZ210065, AZ220033, AZ220036, AZ220042, AZ220046, AZ220049, AZ220053, AZ220056, AZ220059, AZ220061, AZ220065, AZ220071, AZ220074, AZ220077, AZ220122, AZ220126, AZ220151, and AZ220155

More information regarding the extended lots can be found on the Administration for Strategic Preparedness & Response (ASPR) website.

Reporting Serious Adverse Events and Medication Errors:

Under the EUA, all serious adverse events and medication errors potentially related to EVUSHELD use must be reported within 7 calendar days from the healthcare provider's awareness of the event.

Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program using one of the following methods:

• Complete and submit the report online: www.fda.gov/medwatch/report.htm

• Complete and submit a postage-paid Form FDA 3500 (https://www.fda.gov/media/76299/download) and return by:

- Mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or
- Fax (1-800-FDA0178)

• Call 1-800-FDA-1088 to request a reporting 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.

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Sincerely,

Rachele Berria, MD PhD
Vice President and Medical Head, US BioPharmaceuticals
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