AstraZeneca

IMPORTANT PRESCRIBING INFORMATION

Subject: Updated EVUSHELD Emergency Use Authorization (EUA) Warnings and Precautions

Dear Healthcare Provider:

The EVUSHELD (tixagevimab co-packaged with cilgavimab) Warnings and Precautions under the Emergency Use Authorization (EUA) have been updated. Changes include information added regarding potential risk of COVID-19 due to SARS-CoV-2 viral variants not neutralized by EVUSHELD (section 5.3).

The revised Warnings and Precautions are as follows:

5.3 Risk for COVID-19 Due to SARS-CoV-2 Viral Variants Not Neutralized by EVUSHELD

Certain SARS-CoV-2 viral variants may not be neutralized by monoclonal antibodies such as tixagevimab and cilgavimab, the components of EVUSHELD. EVUSHELD may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. The *in-vitro* neutralization activity of EVUSHELD against SARS-CoV-2 viral variants is shown in Table 6 *[see Microbiology (12.4)]*.

Inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 viral variants not neutralized by EVUSHELD. If signs or symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate. Symptoms of COVID-19 may include: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea[1].

HEALTHCARE PROVIDER ACTION

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

Decisions regarding the use of EVUSHELD should take into consideration what is known about the characteristics of the circulating SARS-CoV-2 viral variants, including local epidemiological data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions).

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:

[1] For additional information on the symptoms of COVID-19, please see https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.

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://contact.medical.astrazeneca.com, or calling AstraZeneca at 1-800-236-9933.

Sincerely,

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