



July 18, 2022

FDA authorizes revisions to Evusheld® dosing

On June 29, 2022, the U.S. Food and Drug Administration (FDA) revised the <u>Evusheld Fact Sheet for Healthcare Providers</u> to <u>recommend repeat dosing every six months</u> with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. The previous Fact Sheet for Healthcare Providers did not provide a specific recommendation on the dosing interval.

There are different variants (and subvariants) of SARS-CoV-2, and FDA continues to evaluate how well Evusheld (tixagevimab co-packaged with cilgavimab) neutralizes them. Currently, the Omicron BA.2, BA.2.12.1, BA.4, and BA.5 subvariants are circulating in the United States. Nonclinical data and pharmacokinetic modeling suggest that activity against these subvariants may be retained for six months at drug concentrations achieved following an Evusheld dose of 300 mg of tixagevimab and 300 mg cilgavimab.

The FDA will continue to monitor the neutralizing activity of Evusheld against emerging SARS-CoV-2 variants and will provide additional updates as needed. For further details, please refer to the Frequently Asked Questions for Evusheld.

References:

1. U.S. Food and Drug Administration. FDA Authorizes Revisions to Evusheld Dosing. Published June 29, 2022.