Direct Healthcare Professional Communication

November 2022

Tixagevimab + Cilgavimab– Updated dosage recommendations for pre-exposure prophylaxis

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- The Evusheld (Tixagevimab and Cilgavimab) dosage recommendations have been updated.
- Specifically, the initial dose for pre-exposure prophylaxis has been increased from 300 mg administered intramuscularly (IM) to 600 mg IM (300 mg of tixagevimab and 300 mg of cilgavimab), and guidance on repeat dosing has also been provided.[1]
- These updated dose recommendations are based on the totality of the available data including clinical pharmacology, pharmacokinetics, antiviral activity and clinical trial data.
- Tixagevimab + Cilgavimab has been studied for the prophylaxis of COVID-19 at the 300 mg dose[2]. The clinical safety of 600 mg dose for prophylaxis use is supported by safety data from TACKLE in patients with mild to moderate COVID-19.

Background on the safety concern

The updated dosing recommendations are as follows1:

Initial Dosing:

The initial dosage of Evusheld is 600 mg (300 mg of tixagevimab and 300 mg of cilgavimab) administered as two separate, 3.0 mL sequential intramuscular (IM) injections.

Dosing for Individuals Who Initially Received 150 mg of Tixagevimab and 150 mg of Cilgavimab:

- Individuals who initially received 150 mg tixagevimab and 150 mg cilgavimab should receive 300 mg tixagevimab and 300 mg cilgavimab as soon as possible.
- A minimum dosing interval of 3 months should be maintained between administration of the initial (150 mg tixagevimab and 150 mg cilgavimab) dose and second (300 mg tixagevimab and 300 mg cilgavimab) dose.

Repeat Dosing:

For individuals who require repeat dosing for ongoing prevention of COVID-19, subsequent doses of 600 mg (300 mg tixagevimab and 300 mg cilgavimab) should be given once every 6 months.

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

Healthcare Provider Action:

Each carton of Evusheld contains two vials (one vial of 150 mg/1.5 mL tixagevimab and one vial of 150 mg/1.5 mL cilgavimab); therefore, you will need **2 cartons** for a 600 mg dose.

Please note the product preparation of a 600 mg (300 mg tixagevimab and 300 mg cilgavimab) dose as shown in Table 1.[1]

Table 1. Initial Dosing of 300 mg of Tixagevimab and 300 mg of Cilgavimab

Dose* (tixagevimab and cilgavimab) **600 mg (2 cartons)**	**Antibody dose**	**Number of vials needed**	**Volume to withdraw from vials**
	tixagevimab 300 mg	2 vials	3 mL * **(1.5 ml from each vial into the same syringe)**
	cilgavimab 300 mg	2 vials	3 mL * **(1.5 ml from each vial into the same syringe)**

*Each carton of EVUSHELD contains one vial of tixagevimab 150 mg/1.5 mL and one vial of cilgavimab 150 mg/1.5 mL. The 300 mg of tixagevimab and 300 mg of cilgavimab doses are to be administered as separate, consecutive intramuscular injections. Withdraw the 3 mL of tixagevimab solution and 3 mL of cilgavimab solution into TWO separate syringes. Each vial has overfill to enable withdrawal of 1.5 ml from each vial. **Any leftover product should be discarded.**

Healthcare providers should refer to the and stay abreast of any changes to the label implemented by local Health Authorities.

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

References

1. FDA https://www.fda.gov/media/156618/download
2. Levin MJ, Ustinaowski A, De Wit S, et al. Intramuscular AZD7442 (tixagevimab/cilgavimab) for prevention of COVID-19 [article and supplementary appendix]. *N Engl J Med*. 2022. https://doi.org/10.1056/NEJMoa2116620.
3. Montgomery H, Hobbs R, Padilla F, et al. Efficacy and Safety of Intramuscular Administration of Tixagevimab-Cilgavimab for Early Outpatient Treatment of COVID-19 (TACKLE): a Phase 3, Randomised, Double-Blind, Placebo-Controlled Trial [article and supplementary appendix]. *Lancet Respir Med*. 2022. https://doi.org/10.1016/ S2213-2600(22)00180-1

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470