



22 AUG 2022

IMPORTANT PRESCRIBING INFORMATION

Subject: Proper Preparation and Administration of TPOXX[®] (tecovirimat) Injection for Intravenous Infusion

Dear Healthcare Provider:

The purpose of this letter is to make you aware that TPOXX[®] (tecovirimat) injection should only be prepared in a syringe(s)* of suitable size and administered for intravenous infusion via syringe pump, as detailed in the FDA approved prescribing information. Due to the high content of the inactive ingredient Hydroxypropyl Betadex in the tecovirimat injection formulation there is an elevated risk for leaching of impurities into the solution during preparation and administration when equipment other than syringes/syringe pumps are used. Therefore, the use of empty or prefilled infusion bags are not recommended for use with TPOXX[®] (tecovirimat) injection. SIGA also recommends against the use of glass IV bottles for preparation and administration of TPOXX[®] (tecovirimat) injection.

For additional information about TPOXX[®], including the full FDA approved Prescribing Information, please visit <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fce826ab-4d6a-4139-a2ee-a304a913a253>

Reporting Serious Adverse Events and Medication Errors:

Report life-threatening or serious adverse events and/or medication errors associated with TPOXX by completing a PDF MedWatch Form [226KB, 3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Sincerely,

SIGA Technologies, Inc.

*Dependent on the size of syringe available with the syringe pump system, and the specific dose, two separate syringes may be needed to administer the full dose in some cases.