SIGA Technologies Inc.

29 JUL 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:**

Healthcare providers are required to report all serious adverse events and medication errors when using TPOXX® to FDA's MedWatch program using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- 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 208529787, or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form.

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.