Smallpox Antiviral

Implementation Date: December 09, 2022

This policy is evergreen and will be updated as new information becomes available.

<table>
<tr><td colspan="4">Please consult the Product Monograph[1] for further information about the medication.</td></tr>
<tr><td></td><td colspan="3">TPOXX® Tecovirimat Capsules</td></tr>
<tr><td>Manufacturer</td><td colspan="3">Sponsor: SIGA Technologies, Inc. (USA distributor: Innomar Strategies, Inc.)</td></tr>
<tr><td>Licensed use</td><td colspan="3">Treatment of human smallpox disease in adult and pediatric patients weighing at least 13 kg.</td></tr>
<tr><td>Off-license use</td><td colspan="3">• Treatment of mpox disease in adults and children weighing at least 13 kg.
Notes:
• TPOXX® is approved by Health Canada under the provisions of the Extraordinary Use New Drug regulations.
• This antiviral is available in Alberta for off-license mpox treatment, and will only be available to individuals as prescribed by their physician.</td></tr>
<tr><td>Indications for use of provincially funded antiviral[2]</td><td colspan="3">• Antiviral treatment for mpox disease should be considered for individuals who have a documented laboratory-confirmed diagnosis and who are:
- Severely ill, requiring hospitalization or care in intensive care setting.
- Pregnant, severely immunocompromised with progressive infection, or have keratitis.
- At very high risk of severe illness with progressive infection, including those who are moderately immunocompromised, younger than 10 years of age, or have atopic dermatitis with significant skin lesions.
• Immunized individuals (those who received Imvamune) who display progressive infection could be eligible for TPOXX if they meet the criteria outlined above.
<u>Note:</u> Regardless of whether the individual meets these criteria or not, all mpox cases must be reported to the Zone MOH.</td></tr>
<tr><td>Dose and Schedule[1]</td><td colspan="3">Adults
• The recommended dosage is 600 mg (3 capsules) twice daily for 14 days.
Children and adolescents who weight at least 13 kg
The recommended dosage for pediatric patients is based on weight starting at 13 kg as shown in the table below.</td></tr>
<tr><td></td><td>Body Weight</td><td>Dosage</td><td>Number of Capsules</td></tr>
<tr><td></td><td>13 kg to less than 25 kg</td><td>200 mg twice daily</td><td>Contents of 1 capsule twice daily</td></tr>
<tr><td></td><td>25 kg to less than 40 kg</td><td>400 mg twice daily</td><td>Contents of 2 capsules twice daily</td></tr>
<tr><td></td><td>40 kg and above</td><td>600 mg twice daily</td><td>Contents of 3 capsules twice daily</td></tr>
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	Notes • TPOXX should be taken within 30 minutes after a meal of moderate or high fat to ensure proper absorption. • If a dose is missed, the patient should be advised to take it as soon as they remember, and then continue with the next dose at the proper time interval. • No dose adjustment is required for patients with renal or hepatic impairment. **Preparation instructions for pediatric patients and those who cannot swallow capsules** • Carefully open the capsule so that the contents do not spill or escape into the air. • Hold the capsule with the cap facing up and pull the cap away from the body of the capsule. • Use a small container for mixing. • Mix the entire contents of the required number of capsules with at least 30 mL of liquid (e.g. milk, chocolate milk) or soft food (e.g. yogurt, applesauce). • The whole mixture should be taken within 30 minutes after mixing and within 30 minutes of eating a meal.
Route	Oral
Contraindications[1]	• Known hypersensitivity to any component of TPOXX.
Precautions[1]	• Co-administration of repaglinide may cause hypoglycemia. • TPOXX may reduce the effects of midazolam. • Efficacy may be reduced in immunocompromised individuals, based on studies demonstrating reduced efficacy in immunocompromised animal models. • Co-administration of TPOXX with smallpox vaccine may reduce the immune response to the vaccine. • TPOXX has been reported to cause prolongation of the QT interval.
Possible reactions	See product monograph.[1]
Storage and Handling[1]	Store at room temperature +15°C to +25°C.
Pregnancy	• TPOXX has not been studied in pregnant individuals, and should not be used unless the benefits outweigh the risks[1].
Lactation	• It is unknown if TPOXX is excreted in human milk[1]. • The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TPOXX [1].
Program Notes	2022, June 07 – Implemented in Alberta 2022, December 01 – Updated to expand eligibility

References

[1] SIGA Technologies, Inc. (2021, November 29). PRTPOXX® Tecovirimat Capsules. https://pdf.hres.ca/dpd_pm/00063782.PDF *Product Monograph.*

[2] CADTH. (2022, September). Tecovirimat (TPOXX): Update. www.cadth.ca/sites/default/files/attachments/2022-09/HC0040-Tecovirimat-%28Tpoxx%29-Update-sep28.pdf. *Updated report.*

