Ontario

Ministry of Health

Tecovirimat (TPoxx®) Antiviral for Mpox-Guidance for Health Care Providers and Tpoxx® Order Form

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This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

The virus that causes mpox is distinguished by two separate genetic clades:

- **Clade I**: Sub-clade Ia is endemic to Central Africa and causes more severe illness and deaths than clade II. Sub-clade Ib emerged in the Democratic Republic of Congo (DRC) in 2023 and is spreading through direct contact, primarily through sexual networks.
- **Clade II:** This clade is endemic to West Africa and is associated with less severe illness and deaths than clade I. Sub-clade IIb was responsible for the 2022 global mpox outbreak that primarily affected adults who identified as men who have sex with other men.

Ontario continues to monitor for cases of mpox (clade I and II) and is working collaboratively with health care providers, Public Health Ontario (PHO) and the Public Health Agency of Canada (PHAC) to address health risk(s). Guidance will be updated as new information becomes available and epidemiology evolves.

Information related to mpox and vaccination in this document is based on the current epidemiology in Ontario and most recent evidence.

Tecovirmat (TPoxx®) Antiviral Medication

The antiviral drug tecovirimat (TPoxx®) is a medication that inhibits the production of an orthopoxviral envelope protein required for cell-to-cell viral dissemination.

In Canada, TPoxx® is authorized for sale and use for the treatment of human smallpox disease via its Extraordinary Use New Drugs (EUNDS) pathway. This pathway was developed to authorize drug products based on limited clinical information in humans.

TPoxx® can also be used off-label for the treatment of mpox in adults and pediatric patients weighing at least 13 kg (29 lbs). See **Table 1** below for dosage information.

There is no data on the optimal timing to initiate therapy, although it is likely to be most beneficial if started earlier in the course of infection.

Table 1: Recommended dosing for pediatric and adult patients

Body Weight	Dosage (200 mg/capsule)
13 kg to less than 25 kg	**PO BID x 14 days**
25 kg to less than 40 kg	**PO BID x 14 days**
40 kg and above	**PO BID x 14 days**

* Note: TPoxx® should be taken within 30 minutes after a full meal of moderate or high fat.

For more information regarding the recommended adult and pediatric dosage and preparation instructions, see the product monograph.

Summary of Scientific Evidence for TPoxx®

TPoxx® has been used off-label in Canada to treat mpox infections since the 2022 global outbreak of mpox clade II. This use was largely based on in vitro and animal studies, as well as limited safety studies and case reports in humans. The primary goals of this off-label use were to prevent or mitigate severe outcomes, including death, especially among high-risk groups such as immunocompromised and pregnant individuals.

Several clinical trials have since examined the safety and efficacy of TPoxx® in treating human mpox infections. Initial results from two large randomized controlled studies demonstrated that, while safe, TPoxx® **did not** reduce the time to resolution of mpox lesions compared to placebo. The findings of these studies suggest that most individuals with mpox who do not have severe disease or risk factors for severe disease are likely to recover with supportive care and pain management alone. These trials excluded pregnant, lactating, and severely immunocompromised individuals, so further research is needed to determine the role of TPoxx® in these populations.

While TPoxx® has not been studied in pregnant people, limited available data suggest potential for intrauterine transmission and that mpox increases the risk of severe maternal disease, miscarriage, and stillbirth. Animal studies suggest no embryo-fetal development toxicity during organogenesis. The background risk of significant congenital disabilities and fetal loss for the indicated population is unknown.

Similarly, there are no human data on the effect of TPoxx® on milk production, its presence in the human milk, or effects on breastfed children. However, one US study reported no medication-related adverse events reported among 11 breastfeeding women who received TPoxx®.

Other clinical trials to evaluate the effectiveness and safety of TPoxx® for the treatment of mpox infection compared to placebo have been conducted both in Canada and internationally; combined results from these trials are expected in the future.

How to Access TPoxx® in Ontario

There is a limited supply of TPoxx® in Canada and access to the drug remains restricted.

Licensed physicians can request TPoxx® for the treatment of mpox infections for patients in exceptional circumstances which are outlined in the next section of this document. Providers should conduct a careful assessment of risks versus potential benefits of treatment for each mpox case, and obtain patient consent for treatment, before requesting TPoxx®. The decision to use TPoxx® in treatment of patients infected with mpox should be done in conjunction with an infectious disease specialist.

All requests for TPoxx® should be sent to the Office of Chief Medical Officer of Health, Public Health at vaccinesupplyandlogistics@ontario.ca. All TPoxx® requests will be evaluated by the ministry of health on a case-by-case basis in consultation with infectious disease specialists in the field.

See **Appendix A** which outlines information required to request access to TPoxx®.

Informed consent guidance is reflected in Appendix B below.

Indications for TPoxx® in Ontario

TPoxx® is not recommended routinely in all cases of mpox.

TPoxx® may be considered in the following **exceptional** circumstances on a case-by-case basis:

- Persons with end-organ manifestations due to mpox infection (e.g., ocular, gastrointestinal, pulmonary, cardiac, neurological, endocrine complications);
- Persons who are severely immunocompromised, such as individuals who are:
    - living with HIV with current CD4 counts < 200/mm3 or with uncontrolled viral loads;
    - receiving active treatment for solid tumour or hematologic malignancies such as chemotherapy, targeted therapies, or immunotherapy, including chimeric antigen receptor T-cell (CAR-T) therapy;
    - recipients of solid-organ transplant and taking immunosuppressive therapy;
    - recipients of hematopoietic stem cell transplant within 2 years of transplantation or taking immunosuppressive therapy;
    - living with an autoimmune disease with immunodeficiency as a clinical component;

    - on treatment with agents such as tumor necrosis factor or high-dose corticosteroids;
- Pregnant or breastfeeding individuals, due to an increased risk of severe disease during pregnancy and the possibility of severe infection in newborns. See below.

Use of TPoxx® in Special Populations

Pediatrics (<13kg)

No data is available to Health Canada.

Health Canada has not authorized an indication for pediatric use in children weighing less than 13 kg.

Pediatrics (≥13kg)

Health Canada has authorized an extraordinary use indication for pediatric patients weighing ≥ 13 kg. TPoxx® has not been studied in children and adolescents 17 years of age and younger.

Breastfeeding individuals

It is unknown if TPoxx® is excreted in human milk.

The developmental and health benefits of breastfeeding should be considered, along with the person's clinical need for TPoxx® and any potential adverse effects on the breastfed child from TPoxx® or the underlying condition of the individual.

Geriatrics (65 years)

Clinical studies of TPoxx® did not include sufficient numbers of subjects 65 years of age and older to determine whether the safety profile of TPoxx® is different in this population compared to younger individuals.

Precautions related to TPoxx® Usage

The following precautions are strongly recommended when prescribing TPoxx® to patients with specific medical considerations, which can be found in the product monograph and summarized below.

Endocrine and Metabolism

Co-administration of repaglinide and TPoxx® may cause mild to moderate hypoglycemia. Monitor blood glucose and monitor for hypoglycemic symptoms when administering TPoxx® with repaglinide.

Immune Dysfunction

TPoxx® efficacy may be reduced in immunocompromised patients based on studies demonstrating reduced efficacy in immunocompromised animal studies.

QTc Interval Prolongation

TPoxx® has been reported to cause prolongation of the QTc interval. Caution should be observed if TPoxx® is administered to patients who are considered to be at high risk of the torsade de pointes arrhythmia, including but not limited to, those with congenital or acquired long QT syndrome, other cardiac disease, electrolyte depletion (e.g., hypokalemia, hypomagnesemia, or hypocalcemia) or conditions that lead to electrolyte depletion, or in situations of concomitant treatment with Class IA or Class III antiarrhythmics or other QTc- prolonging drugs.

Fertility

There is no data on the effects of TPoxx® on fertility in humans. In male mice, decreased fertility associated with testicular toxicity (increased percent abnormal sperm and decreased sperm motility) was observed at 1000 mg/kg/day (approximately 24 times the human exposure at RHD).

Potential Side Effects of TPoxx®

In adults, the most commonly reported side effects were headache and nausea followed by abdominal pain and vomiting.

Less common adverse reactions can include:

- Gastrointestinal: dry mouth, chapped lips, dyspepsia, eructation, and oral paresthesia.
    - General pyrexia, pain, chills, malaise, and thirst.
    - Investigations: abnormal electroencephalogram, hematocrit decreased, hemoglobin decreased, heart rate increased and QTc prolongation.
    - Musculoskeletal and connective tissue: arthralgia and osteoarthritis.
    - Nervous system: migraine, disturbance in attention, dysgeusia and paresthesia.
    - Psychiatric: depression, dysphoria, irritability, and panic attack.
    - Respiratory, Thoracic and Mediastinal Disorders: oropharyngeal pain.
    - Skin and subcutaneous tissue: palpable purpura, rash, pruritic rash, facial redness, facial swelling, and pruritus.

Contraindications to TPoxx®

Individuals who are hypersensitive to this drug or to any ingredient in the formulation should not receive it. A list of ingredients can be found in the product monograph.

Storage Conditions

Store TPoxx® at room temperature (+15°C to +25°C).

This medicine should not be used after the expiry date shown on the bottle.

Additional Resources

European Centre for Disease Prevention and Control - Factsheet for health professionals on mpox (monkeypox)

Ontario Ministry of Health - Mpox Virus

Public Health Agency of Canada - Mpox (monkeypox)

Public Health Ontario – Mpox (formerly known as monkeypox)

World Health Organization – Mpox (monkeypox) Key Facts World Health Organization - Mpox (monkeypox)

Appendix A – Tpoxx® Order Form

Clinicians must provide the following information for each patient that has consented to receive TPoxx® at the time they are submitting their request. Failure to provide the information below in full may result in requests being delayed or denied.

Submit the form below to vaccinesupplyandlogistics@ontario.ca

A. REQUESTER INFORMATION

Name of requesting clinician: _____

Contact information of requesting clinician: _____

B. PATIENT INFORMATION

Age: _____Sex and gender: _____

MPOX test date: _____

Test status: positive pending negative/not tested

Current disposition: hospitalized outpatient

Dose Requested _____

Clinical indication for treatment (see eligibility above):

_____

_____

_____

_____

C. DELIVERY INFORMATION

Primary contact name:_____

Primary contact number:_____

Secondary contact name:_____

Secondary contact number:_____

OGPMSS ID # (if known):_____

Public Health Unit:_____

Name of delivery site:_____

Delivery site address:_____

Delivery hours:_____

Special instructions:_____

Please send above information to: vaccinesupplyandlogistics@ontario.ca

Appendix B: Informed Consent

The *Health Care Consent Act, 1996* provides specific information on the consent required for treatment. According to the HCCA, the College of Nurses of Ontario (CNO) and the College of Physicians and Surgeons of Ontario (CPSO) standards, nurses and physicians are accountable for obtaining consent when providing treatment. Therefore, it is the responsibility of the health practitioner proposing the treatment to take reasonable steps to ensure that informed consent for that treatment is obtained.

According to the HCCA, consent to treatment for a capable person is informed if, before giving the consent:

a. the person received the information about the treatment that a reasonable person in the same circumstances would require to make a decision; and

b. the person received responses to their requests for additional information about the treatment.

This information must include:

- The nature of the treatment
- The expected benefits of the treatment
- The material risks of the treatment
- The material side effects of the treatment
- Alternative courses of action
- The likely consequences of not having the treatment

The elements required for consent to treatment include:

- The client must have the capacity to consent
- The consent must relate to the treatment
- The consent must be informed
- The consent must be given voluntarily
- The consent must not be obtained through misrepresentation or fraud

Evidence of Consent:

Although the HCCA states that consent to treatment may be expressed or implied (i.e., written or verbal), the CNO and CPSO strongly advise nurses and physicians to document that consent was obtained from the client. Examples include: (1) a signed consent form and/or (2) documented consent in the client's health records.