Hôpitaux Universitaires Genève

RCP

Réunion de comité multidisciplinaire

Déploiement du tecovirimat en Suisse

Einsatz von tecovirimat in der Schweiz

10 août 2022

Group composition

Responsibility	Alexandra Calmy
Medical coordinator	Matthias Cavassini (FR), Jan Fehr (G)
MD (sites)	Anna Hachefeld, Benjamin Hampel, Vanessa Christinet, Dominique Braun/Huldrych Gunthard (TBD), Gilles Eperon
Clinical pharmacologist	Roselyne Ing Lorenzini
Pharmacy	Hôpitaux Universitaires de Genève
Virologist (CRIVE)	Sabine Yerly, Manuel Schibler, Pauline Vetter, Frédérique Jacquerioz, Laurent Kaiser
Dermatology	Laurence Toutous-Trellu
Community representative	Florian Vock
Specialist on a case-by-case basis	Ophthalmologist, obstetrician, tropical medicine, pediatrician, intensivist

Relates to (patient sticker):

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Check-list for obtaining Tecovirimat

Checking Tecovirimat indication:

☐ Confirmed Monkeypox virus (MKPV) infection

☐ PCR positive (any site) at the time of the treatment decision

☐ SSI-validated situation for treatment

- ☐ Patient **at risk for severe disease**
  - ☐ Immunocompromised or
  - ☐ Pregnant woman pending a specialized opinion or
  - ☐ Children below 12 yo pending a specialized monitoring by a pediatrician
- ☐ Patients with a **severe disease presentation** with many extensive lesions, or confluent lesions leading to functional inability (throat or genital mucosal lesion, eyes) or uncontrollable discomfort.
- ☐ **Patients hospitalized** with organ dysfunction (encephalitis, sepsis) or hemorrhagic lesions

The patient is meeting one of these indications: ☐ YES ☐ NO

The patient is not exactly meeting one of these indications: please be more explicit on the reason for treatment request:

Checking the absence of tecovirimat contra-indication

☐ No known hypersensitivity to the active substance or to any of the excipients (see list below)

Reminder of situations with special warnings requiring precautions for use, dosage adaptation and/or close monitoring that may influence therapeutic decision:

- Repaglinide co-administration
- Midazolam co-administration
- Co-administration with enzymatic inhibitors/inducers of UGT1A1, 1A3 ou 1A4
- Co-administration with cytochrome P450 (CYP)3A and CYP2B6 substrates
- Severe renal impairment (no adaptation needed but no experience in such situations)
- Severe hepatic impairment (no experience in such situations)
- Pregnant or breast-feeding woman (upon specialized advice)
- Children up to 6 kg (upon specialized advice)

List of excipients contained in tecovirimat:

Capsule content

- Silica, hydrophobic colloidal
- Croscarmellose sodium (E468)
- Hypromellose (E464)
- Lactose monohydrate
- Magnesium stearate
- Cellulose, microcrystalline (E460)
- Sodium laurilsulfate (E487)

Capsule shell

- Gelatin
- Brilliant blue FCF (E133)
- Erythrosine (E127)
- Sunset yellow (E110)
- Titanium dioxide (E171)

Printing ink

- Shellac (E904)
- Titanium dioxide (E171)
- Isopropyl alcohol
- Ammonium hydroxide (E527)
- Butyl alcohol
- Propylene glycol
- Simeticone

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RCP decision

All patients should receive an information to choose to enter the MOSAIC observational cohort. Pregnant women should be encouraged to be included also in the POXPREG cohort (Registry on Monkeypox and pregnancy).

Date: _____

Responsible MD for the RCP decision (from another center) _____ **Signature**

Specialized advice (if applicable) _____ **Signature**

Responsible MD for patient's care in the HUG site (one of the six):

Dr. Pauline VETTER	**Dr. Stefano MUSUMECI**
Dr. Manuel SCHIBLER	**Prof. Alexandra CALMY**
Dr Frédérique JACQUERIOZ	**Dr Gilles EPERON**

OR:

Delegated person _____ **Signature**

BIP Infectious diseases cadre: 022 37 29805

☐ Yes Tecovirimat will be provided for this patient (2 bottles of 42 tablets of 200 mg)

Dosing issues: 600 mg oral, bid in adults and children >40 kg. (13-25 kg: 200 mg bid; 25-40 kg: 400 mg bid) (One tablet is 200 mg) to be taken 30 minutes following a fat rich meal. For patients unable to swallow, the capsule can be opened and mixed with a yoghurt or milk.

Treatment duration expected: _____

Specific Surveillance needed? ☐ YES ☐ NO

Patient consent form signed? ☐ YES ☐ NO

Participation to the Mosaic or Poxpreg study? ☐ YES ☐ NO

If Yes, please state patient ID : [C][H][___][___][___] – [___][___][___][___]

Clinical outcome form to be filled and send back to Alexandra Calmy

☐ No Tecovirimat is likely not needed for this patient at this time. Reasons: