MEDICLINIC

COVID-19 INFORMATION

COVID-19 UPDATE

PHARMACY PROCESS

IVERMECTIN FOR COVID-19 TREATMENT

Version 4: What is new?

Medical practitioners may apply to use ivermectin under the IVERMECTIN CONTROLLED COMPASSIONATE USE PROGRAMME

Current evidence

Ivermectin is **not approved for the treatment of any viral infection**, including SARS-CoV-2 infection. There is insufficient clinical data to recommend the use of ivermectin for the prophylaxis or treatment of COVID-19 and it is therefore not recommended in evidence-based guidelines.[1,2,3,] SAHPRA stated in a media briefing on 27 January that they remain of the opinion that there is insufficient clinical evidence of effectiveness to make a regulatory decision about the use of ivermectin in humans for COVID-19. [2]

Availability

The South African Health Products Regulatory Authority (SAHPRA) implemented a compassionate use access programme for ivermectin via the legal framework of Section 21 of the Medicines and Related Substances Control Act (101 of 1965 as amended).[3]

AUTHORISATION OF INDIVIDUAL NAMED PATIENTS:
• A registered medical practitioner may apply, via the Section 21 online submission portal, for permission to prescribe ivermectin to an individual, named patient. • In addition, the applicant must notify SAHPRA of the submission of applications for individual named patients by sending a short message service (SMS) to 072 134 4546 and 063 771 8906.
AUTHORISATION OF HEALTHCARE FACILITIES TO HOLD BULK STOCK:
• A licensed healthcare facility (hospital or pharmacy) who holds a section22C(1)(a) dispensing licence may apply for authorisation via the **Section 21 online submission portal facility** to hold emergency stock of an ivermectin product obtained from an authorised importer (as described in 2.1). The intention of this authorisation is to limit the possible delays between obtaining Section 21 approval for an individual, named patient and accessing the ivermectin product requested. • **Section 21 approval for an individual, named patient and accessing the ivermectin product requested**.
CURRENTLY AVAILABLE SECTION 21 PRODUCT (29 JANUARY 2021)

Equity Pharmaceuticals can provide the following product (application forms attached)

- Iverwon (Ivermectin) 6 mg tablets (100 tabs) = R 243.00 excl. vat
- Iverwon (Ivermectin) 12 mg tablets (100 tabs) = R 395.00 excl. vat

MADATORY REPORTING REQUIREMENTS - PRESCRIBING MEDICAL PRACTITIONER

1. SAHPRA ONLINE PROGRESS REPORT

The medical practitioner authorised to prescribe unregistered ivermectin to an individual, named patient **must comply** with the reporting requirements stated in the Section 21 approval. The patient outcomes (both benefits and harms) are to be reported on SAHPRA's COVI-Vig programme. The reporting portal can be accessed by clicking on ONLINE SERVICES and navigating to COVI-Vig reporting system on the SAHPRA website homepage (www.sahpra.org.za) or https://docs.google.com/forms/d/e/1FAIpQLSe1OwsYZeohuq3Lnb6j61a1IYRbS0xEhdzVmosAlw5Zomh82w/viewform

2. MEDICLINIC EXPERIMENTAL TREATMENT FORM

Available on the Intranet

Drug information

DOSAGE

In the absence of approved guidance for use, there is currently no standardisation of dose or indication for use.

ADVERSE REACTIONS / PRECAUTIONS

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified.[5]

>10%:

- Dermatologic: Pruritus (3%; Mazzotti reaction, associated with onchocerciasis: 28%), dermatological reaction (Mazzotti reaction, associated with onchocerciasis: 23%; includ
- Hematologic & oncologic: Lymphadenitis (Mazzotti reaction, associated with onchocerciasis: 1% to 14%)
- Neuromuscular & skeletal: Arthralgia (Mazzotti reaction, associated with onchocerciasis: ≤9%), synovitis (Mazzotti reaction, associated with onchocerciasis: ≤9%)
- Miscellaneous: Fever (Mazzotti reaction, associated with onchocerciasis: 23%)

1% to 10%:

- Cardiovascular: Tachycardia (4%), peripheral edema (3%), facial edema (1%), orthostatic hypotension (1%)
- Central nervous system: Dizziness (3%)
- Gastrointestinal: Diarrhea (2%), nausea (2%)
- Hematologic & oncologic: Eosinophilia (3%), decreased white blood cell count (3%), increased hemoglobin (1%)
- Hepatic: Increased serum ALT (2%), increased serum AST (2%)

References

1. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/ivermectin/ Accessed on 15 January 2021.
2. SAHPRA. 28 January 2021. SAHPRA Update on the use of ivermectin comments on Ivermectin available at https://www.sahpra.org.za/press-releases/update-on-the-use-of-ivermectin-in-the-prevention-or-treatment-of-covid-19/
3. SAHPRA. 28 January Section 21 Ivermectin Controlled Compassionate-use Programme. Available at https://www.sahpra.org.za/wp-content/uploads/2021/01/Section_21_Ivermectin_Controlled_Compassionate-Use-Programme_Jan21_FINAL.docx.pdf
4. Lexicomp Online