

CORONAVIRUS UPDATE #05

- Wash your hands for at least 20 seconds with soap & water
- Keep at least 2 metres away from others
- STAY AT HOME
- Always wear a cloth mask when out in public

IVERMECTIN AS A COVID-19 TREATMENT: FEDHEALTH'S POSITION

1. What is ivermectin?

Ivermectin is an anti-parasitic drug that is used to treat parasitic infections like onchocerciasis, intestinal strongyloidiasis, head lice, rosacea, and scabies¹. It is also widely used as an anti-parasitic in animals in formulations intended specifically for animal use.

Ivermectin has been proposed as a potential therapy against SARS-CoV-2 based on in vitro cell culture analysis. However, ivermectin is not approved for the treatment of any viral infection, including SARS-CoV-2 infection.

2. What's the hype about?

Earlier in 2020, the FDA issued a warning that ivermectin products intended for use in animals should not be used to treat COVID-19 in humans⁴.

There are reports of ivermectin use in the management of patients hospitalised for COVID-19 which has drawn media attention and social media promotion of the repurposing of the medicine for this indication⁵.

No ivermectin products are locally approved by the South African Health Products Regulatory Authority (SAHPRA) for use in humans. On 28 January 2021, SAHPRA released a document to clarify the process to follow for controlled compassionate access to ivermectin in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).³

3. What is Fedhealth's position on ivermectin?

Various clinical trials assessing the use of ivermectin in the management of COVID-19 are currently underway. Results from one retrospective analysis concluded that **the association of ivermectin with a lower mortality during treatment of COVID-19 needs to be confirmed in randomised, controlled trials.** In addition, a preprint meta-analysis by Hill et al concluded that large controlled, randomised trials are required to provide sufficient results for review by regulatory authorities¹⁶.

Furthermore, **there is no consensus on the established safe and efficacious dose of ivermectin for the treatment or prophylaxis of COVID-19.** Ivermectin use in the management of COVID-19 patients is not included in local⁹ and international clinical guidelines^{10,20}. In addition, no ivermectin products have been locally approved for human use and the experimental use of ivermectin in the treatment and prevention of COVID-19 infections will require access in terms of Section 21 of the Medicine Act for compassionate use³.

Based on the very limited and low quality data available to support the use of ivermectin for the management of COVID-19, including the lack of safe dosing recommendations and the non-inclusion in local and international guidelines, **the use of ivermectin for the treatment and prophylaxis of COVID-19 is not supported.**

IN CONCLUSION:

Ivermectin has been added to the list of 'investigational drugs' by the Council for Medical Schemes in its **Updated COVID-19 Guidelines**, so discretionary funding rules would apply for medical schemes.

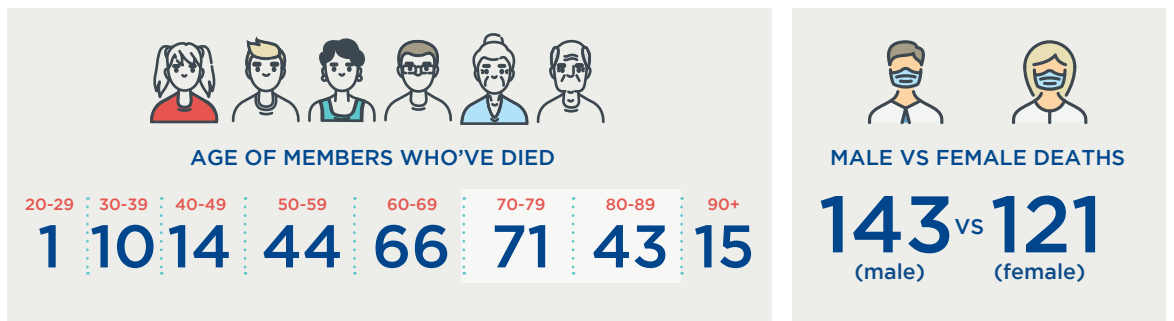
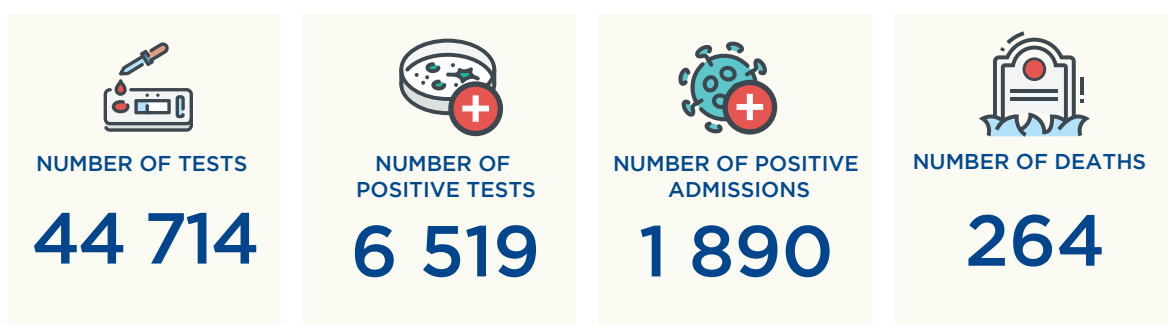
Fedhealth has taken the same funding stance for ivermectin as it has with all other investigational therapies namely, **no upfront funding will be permitted and cases will only be assessed on motivation and on an individual, case-by-case basis.**

References:

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3. SAHPRA, Section 21 Access to Unregistered Medicines 28 January 2021, Ivermectin Controlled Compassionate Use Programme, https://www.sahpra.org.za/wpcontent/uploads/2021/01/Section_21_Ivermectin_Controlled_Compassionate-UseProgramme_Jan21_FINAL.docx.pdf.
4. FDA letter to Stakeholders Do not use ivermectin intended for animals as treatment fo COVID-19 in humans, 10/04/2020, <https://www.fda.gov/safety/medical-product-safety-information/ivermectin-intended-animals-letterstakeholders-do-not-use-humans-treatment-covid-19>.
5. NDOH_Rapid review of Ivermectin for COVID-19 21 December 2020, http://www.health.gov.za/wpcontent/uploads/2020/12/Rapid-review-of-Ivermectin-for-COVID-19_21December2020.pdf.
10. National Institutes of Health (NIH), COVID-19 Treatment Guidelines 2019, Last updated on 17/12/2020, Accessed on 28/12/2020, <https://www.covid19treatmentguidelines.nih.gov/>
16. Hill et al., on behalf of the International Ivermectin Project Team, Preprint, Preliminary Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infections, Research Square, doi:10.21203/rs.3.rs-148845/v1, 19 January 2021, <https://www.researchsquare.com/publication/10.21203/rs.3.rs-148845/v1>
20. Infectious Disease Society of America (IDSA) COVID-19 Treatment Guidelines (IDSA) 02 December 2020, <https://www.idsociety.org/practiceguideline/covid-19-guideline-treatment-and-management/>.

THE LATEST FEDHEALTH COVID-19 STATS

We share Fedhealth's latest COVID-19 statistics with you (as of 15 February 2021).



CO-MORBIDITIES OF MEMBERS WHO HAVE BEEN ADMITTED

	Hyper-tension	Diabetes	Chronic Renal Disease	Oncology	Obe-sity	Cardiac Disease	Asthma	COPD	TB	HIV
COVID-19 survivors	431	246	35	107	17	268	65	11	15	64
COVID-19 deaths	104	57	5	30	2	66	10	0	1	11
Total	535	303	40	137	19	334	75	11	16	75

IMPORTANT CONTACT NUMBERS

Fedhealth Customer Contact Centre: Monday to Thursday 08h30 - 17h00; Friday 09h00 - 17h00. Call 0860 002 153 or email member@fedhealth.co.za
Fedhealth Nurse Line and Emergency Medical Services: 0860 333 432
Paed-IG: 0860 444 128 and **SOS Call Me:** *130*3272*31# Press 1. Emergency Medical Services; 2. Nurse Line; 3. MediTaxi. Visit the **Coronavirus Hub on the Fedhealth website:** <https://fedhealth.co.za/media/2338/fedhealth-coronavirus-faqs-document.pdf> or use the **COVID-19 Chatbot** (go to LiveChat on fedhealth.co.za to select)



IMPORTANT COVID-19 RESOURCES

COVID-19 online resource and news portal: <https://sacoronavirus.co.za/>
 The National Institute for Communicable Diseases (NICD): <https://www.nicd.ac.za/>