

# FAQ: Is Ivermectin a Safe and Effective Treatment for COVID-19?

Ivermectin is an antiparasitic agent that was originally approved by the FDA for treatment of onchocerciasis and intestinal strongyloidiasis in 1998. In a recent study published by scientists in Australia, ivermectin demonstrated *in vitro* activity against SARS-CoV-2, which has led to significant press and inquiries about use of this potential therapy.<sup>1</sup> This FAQ highlights several notable limitations of this study and considerations for use for COVID-19:

- The current study by Caly et al. was published as a “pre-proof”, which means it is still subject to additional edits. The main outcome of the study was reduction in virus detected in cell culture at 48 hours, and ivermectin did result in a 50% reduction in virus.
- The authors report promising “*in vitro*” anti-viral activity of ivermectin against SARS-CoV2, however, it is uncertain whether or not the plasma concentration required to emulate these *in vitro* exposures can be safely achieved in humans. The concentration used in the study by Caly et al. was approximately 50-fold greater than concentrations achieved with current clinical regimens.
- The authors do not recommend ivermectin as a safe and effective treatment option for COVID-19, but rather call for *in vivo* research to further explore their preliminary findings.
- Prior “*in vitro*” studies demonstrated promising anti-viral activity of ivermectin for Dengue virus, which is also a single-stranded RNA virus, but further “*in vivo*” trials have shown no clinical benefits in humans.<sup>2-3</sup>
- Ivermectin is associated with significant side effects, including Mazzotti reaction (dermatological reaction including pruritis and urticaria), lymphadenitis, and arthralgias. In addition, ivermectin can cross the blood-brain barrier and induce encephalopathy, especially in patients in hyperinflammatory states such as COVID-19.<sup>4</sup>
- To date, no clinical trials have demonstrated the safety and efficacy of ivermectin for treatment or prevention of COVID-19 infection.

Overall, we believe ivermectin should not be administered to patients to treat or prevent COVID-19 outside of the clinical trial setting. Although these *in vitro* results are promising, well-controlled clinical trials are needed to demonstrate whether or not this agent can improve symptoms, reduce time to clinical improvement, and decrease mortality.

#### References:

1. Caly L, et al. Antiviral Research 2020. DOI:10.1016/j.antiviral.2020.104787.
2. Tay MY, et al. Antiviral Research 2013;99(3):301-306.
3. Yamasmith E, et al. “Internal Medicine and One Health” 2012: Chonburi, Thailand.
4. Stromectol Package Insert. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/98/50-742s001\\_Stromectol\\_PrntLbl.PDF](https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/50-742s001_Stromectol_PrntLbl.PDF).

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