



PDS Advisory on the Use of Ivermectin for COVID-19

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Overview:

Ivermectin, a broad-spectrum antiparasitic agent, has gained global attention as a possible treatment for COVID-19. For human use, Ivermectin is currently approved by the Food and Drug Administration (FDA) as a prescription drug in topical formulation for the treatment of external parasitic diseases such as scabies, pediculosis and cutaneous larva migrans. For veterinary use, Ivermectin is approved in oral and intravenous formulations to treat internal and external parasites in certain animal species. While there are some studies that suggest potential effectiveness of Ivermectin in the prevention and management of COVID-19, existing data has limitations.

Summary of guidelines/recommendations regarding the use of Ivermectin for COVID-19 treatment:

- World Health Organization: Ivermectin should only be used to treat COVID-19 within clinical trials.
- FDA (USA) : Ivermectin is not approved for use in treating or preventing COVID-19 in humans.
- FDA (Philippines): Ivermectin is not recommended for the treatment of COVID-19. It has not been proven to significantly reduce mortality or improve clinical outcome.
- Philippine Society for Microbiology and Infectious Diseases (PSMID): There is insufficient evidence to recommend the use of ivermectin for the treatment of patients with COVID-19 infection (*very low quality of evidence*).
- Philippine COVID-19 Living CPG Reviewers of the UP-NIH ICE and Consensus Panel Representatives of FDA-DOH, PMA, PCP, PAFP, POGS, PCEM, PSGIM, PCCP, PSPHP and PSMID: Based on the current evidence from randomized controlled trials, Ivermectin is not recommended for the treatment of COVID-19. It has not been proven to significantly reduce mortality or improve other clinical outcomes.
- Merck/MSD (manufacturer of Ivermectin – Stromectol): Available data do not support the safety and efficacy of Ivermectin beyond the doses and populations indicated in the regulatory agency-approved prescribing information.
 - No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies
 - No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and;
 - A concerning lack of safety data in the majority of studies.

Furthermore, the Philippine FDA states that **“currently, there is no registered Ivermectin oral formulation for human use”**.

Based on the aforementioned, the PDS members are:

- Advised against the use of Ivermectin for the prevention and treatment of COVID-19 because there is no conclusive clinical data to support its safety and efficacy.
- Encouraged to continue to monitor emerging evidence on the safety and efficacy of Ivermectin for the prevention and treatment of COVID-19.
- Discouraged from procuring and dispensing Ivermectin for COVID-19 treatment and be reminded that under the Republic Act No. 9711 or the “Food and Drug Administration Act of 2009”, the sale of any unregistered health product is prohibited.
- Advised to adhere to the current standard guidelines for the prevention and treatment of COVID-19.



Lastly, we would like to call for your cooperation in educating the public regarding this issue. We do believe that it is everyone's intention to help our fellow countrymen and to give hope in these disconsolate circumstances. However, let us remember to carry our oath as physicians: "*Primum non nocere*"- First, do no harm.

Addendum:

The Philippines' Food and Drug Administration (FDA) on Thursday, April 8, issued a limited permit for an undisclosed hospital to use Ivermectin as treatment for COVID-19. A compassionate special permit (CSP) allows for the limited use of investigational drugs or unregistered drugs. The use of the drug is limited to the hospital for which the permit is granted, which means it cannot be sold in the market. Having this permit does not guarantee either that the drug is proven effective or already recommended by the FDA.

The recommendations on the use of ivermectin for the management of COVID-19 were based on current evidences from sources and references included in the advisory. As new evidence may emerge, this advisory can be updated accordingly.

References:

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2. Speare R, Durrheim D. Mass treatment with ivermectin: an underutilized public health strategy [Internet]. Available at: <https://www.who.int/bulletin/volumes/82/8/editorial30804html/en/>.
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5. Institute of Clinical Epidemiology, National Institutes of Health, UP Manila. Philippine COVID-19 Living Recommendations [Internet]. Available at: <https://www.psmid.org/philippine-covid-19-living-recommendations/>.
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7. Rappler. Magsambol B. Hospital gets limited permit to use ivermectin for COVID-19 treatment. 8 Apr 2021 [internet]. Available from: <https://www.rappler.com/nation/hospital-gets-limited-permit-use-ivermectin-covid-19-treatment-april-2021>.