

Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
August 25, 2021

Warning Issued by Food and Drug Administration (FDA) and World Health Organization (WHO) on Use of Ivermectin

FDA and WHO Guidance Concerning Use of Ivermectin

The FDA has not approved or issued an Emergency Use Authorization (EUA) for ivermectin use in treating or preventing COVID-19 in humans. Ivermectin is not an anti-viral and is approved at specific doses for specific conditions. There are two forms available for human use, tablets to treat intestinal strongyloidiasis and onchocerciasis and a topical to treat head lice and skin conditions such as rosacea. Ivermectin is usually given as a single dose on an empty stomach followed by a full glass of water when used for FDA-approved indications. Side effects occur, and drug interactions are common.

The FDA has issued a specific warning against the use of large doses of the drug indicating this can be dangerous and cause serious harm. The agency has also advised against human use of ivermectin produced for animals, such as cows and horses, as the doses are much higher and could contain ingredients intended only for animals and are thus harmful to humans. <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

The WHO has specifically indicated that ivermectin should only be used within clinical trials. The WHO *Therapeutics and COVID-19: living guideline* contains the Organization's most up-to-date recommendations for the use of therapeutics in the treatment of COVID-19 and can be found at WHO's [guidelines on COVID-19 treatments](#)

While there is some information in small studies showing that the drug may be of some clinical benefit in the treatment of COVID-19, other studies have shown no benefit. The drug is not FDA EUA authorized or approved for COVID-19 and there are available drugs including monoclonal antibodies which are FDA EUA authorized for COVID-19 post-exposure prophylaxis and treatment and COMIRNATY (COVID-19 vaccine, mRNA) now has full FDA-approval and two other vaccines in the U.S. are FDA-EUA authorized.

Side Effects, Hospitalizations, and Deaths

Ivermectin is not without side effects even at the single dose and with the doses being given or found in livestock products the risk of overdosing increases as does the severity of side effects and drug interactions. The actual list of significant and serious drug interactions is huge. Noted interactions occur with common medications which include but are not limited to allergy medicines, antibiotics, anticonvulsants, antidepressants, benzodiazepines, some anti-hypertensive medications, blood thinners, and many others. Common side effects for ivermectin include pruritus, dizziness, headache, nausea, diarrhea, and muscle pain. More serious adverse reactions

associated with toxicity and possible ivermectin poisoning documented in clinical literature include loss of consciousness, somnolence, tremor, seizure, hypotension, vomiting, and coma.

Reports of Increased Calls to Poison Control Centers

Nationally and within Alabama the number of calls being received by Poison Control Centers is increasing. In Alabama, as of August 23, 2021, the number of calls from persons taking ivermectin have doubled from the prior year. The Alabama Poison Information Center is tracking the number of calls related to ivermectin side effects, toxicity or poisoning. If you have a patient that has taken ivermectin with signs and symptoms consistent with side effects, adverse reactions or toxicity/poisoning, please call the Alabama Poison Information Center at 1-800-222-1222.

Information on Clinical Trials

People including providers interested in seeking information about registered clinical trials for COVID-19 in the United States can search for such information here at [ClinicalTrials.govexternal icon](#).

FDA Frequently Asked Questions and Article

<https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>

<https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>

Information on Monoclonal Antibodies

CMS reimbursement rates for monoclonal antibody administration can be found at:

<https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>

More information about COVID-19 treatment options, including EUA Fact Sheets, can be found at: <https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options>

Providers of monoclonal antibodies for COVID-19 treatment can be found at:

<https://covid.infusioncenter.org/>