



Ivermectin products for animals are not intended for COVID-19 treatment

Published April 21, 2020

What is ivermectin?

Ivermectin is a drug for humans and animals to treat internal and external parasites, including certain types of worms, fleas, ticks, and lice.

What is the role of the FDA?

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and efficacy of human and veterinary drugs. More information about FDA's mission [here](https://www.fda.gov/about-fda/what-we-do)
<https://www.fda.gov/about-fda/what-we-do>

FDA-approved uses of ivermectin

In humans, ivermectin tablets are FDA-approved for treatment of some parasitic worms. Some topical formulations are FDA-approved for the treatment of external parasites; for example, headlice and skin conditions such as rosacea.

In animals, ivermectin is FDA-approved for prevention of heartworm disease in dogs and cats and for treatment of certain internal and external parasites in livestock.

Ivermectin and COVID-19

In the *Antiviral Research* journal article, "The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro," the authors found that ivermectin reduced the growth of the SARS CoV 2 virus in cell culture. This novel coronavirus is the causative agent of COVID-19. Let us be cautious however, because the research was not conducted in animals and people.

As the public became aware of this research paper, there was growing concerns about people wanting ivermectin to treat COVID-19 and self-medicating by taking ivermectin products intended for animals.

What does this mean? There is no scientific proof about the safety and efficacy of ivermectin for treating COVID-19. Based on current scientific reports, we know ivermectin reduces antiviral activity, but we do not know if it reduces the severity of the disease or the disease progression in people infected with COVID-19.

Side effects associated with ivermectin

Side-effects may include skin rash, nausea, vomiting, diarrhea, stomach pain, facial or limb swelling, and neurologic adverse events (dizziness, seizures, confusion). Sudden drops in blood pressure, severe skin rash requiring hospitalization and liver injury (hepatitis) have been reported. Laboratory test abnormalities include decreased white cell blood count and elevated liver enzymes. [Source](https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals) <https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>

Any use of ivermectin for the prevention or treatment of COVID-19 should be avoided as its benefits and safety for these purposes have not been established. Data from clinical trials are necessary to determine whether ivermectin is safe and effective in treating or preventing COVID-19. For more information click [here](https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals), <https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>

What is the process for drug approval?

For a new drug compound to be approved by FDA, different clinical trials need to be conducted including phase I, II, III, and IV trials. The overall objective of these trials is to prove that the new drug is safe and effective for treating a specific condition. As you can imagine, these trials take time. The FDA has created a program to expedite approval for COVID-19 treatments, and ivermectin is not part of that program.

Phases	Subjects: Multiple animal species	Objectives
Phase I	20-80 healthy volunteers	Safety and efficacy testing
Phase II	100+ patients with a condition or disease	
Phase III	1,000+ patients	
Phase IV	Patients	Monitor safety issues

Summary of drug approval process conducted by FDA

Availability of ivermectin products for animals

Ivermectin is an important drug used by pet owners and farmers for parasite control in their animals. Ivermectin should be given to animals following the label directions or as prescribed by your veterinarian. Contact your veterinarian if you are having difficulties locating a particular ivermectin product for your animals.

What is the FDA doing to protect people from fraudulent COVID-products?

FDA is closely monitoring for fraudulent COVID-19 products and has asked major retailers for their help in monitoring online marketplaces for fraudulent COVID-19 products. For more information click [here](https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals), <https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>.

What should you do to reduce your risk of getting infected with the novel coronavirus?

First follow all CDC guidelines

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>.

Stay in touch with your doctor if you become ill. Do not attempt to self-medicate using any human or animal drug.

Resources and more information

- *FDA mission*. <https://www.fda.gov/about-fda/what-we-do>
- *FAQ: COVID-19 and Ivermectin intended for animals*. <https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals>
- *FDA Letter to stakeholders: Do not use ivermectin intended for animals as treatment for COVID-19 in humans*. <https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans>
- *FDA Drug approval process*. <https://www.fda.gov/drugs/drug-information-consumers/fda-drug-approval-process-infographic-horizontal>
- The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 *in vitro*. *Antiviral Research* 178, June 2020, 104787 <https://doi.org/10.1016/j.antiviral.2020.104787>

Authors

Maria Jose Fuenzalida, PhD, Dairy and Livestock Educator, Extension Dane County.

maria.fuenzalidavalenzuela@wisc.edu

Sandra Stuttgen, DVM, Agriculture Educator, Extension Taylor County. sandra.stuttgen@wisc.edu

©2020 The Board of Regents of the University of Wisconsin System