

[Press Release. (Apr. 10, 2020). Letter to Stakeholders re. IVERMECTIN, Coronavirus (COVID-19) Update: Daily Roundup April 10, 2020. FDA. Sources: <https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans> | <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-10-2020>]

FDA Letter to Stakeholders: Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans

Español (</animal-veterinary/product-safety-information/carta-de-la-fda-las-partes-interesadas-no-use-ivermectina-destinada-animales-como-tratamiento-para>).

April 10, 2020

[Notably, no reference or link is made to the **Oct. 08, 1998 FDA approval of IVERMECTIN 3mg and 6mg tablets** that does not contain these caveats below. See Norman Schmuff, Ph.D. Chem. Team Leader, DNDC III. (Oct. 08, 1998). Drug Approval Package to Merck & Co., Inc., Frank Ricci, approving Stromectol (Ivermectin) Tablets, 6 mg, then 3 mg., App. No. 050742s001, Dec. 12, 1997. U.S. FDA. Center for Drug Evaluation and Research. Source: https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/50-742s001_Stromectol_Approv.PDF]

Dear Stakeholder,

The FDA's Center for Veterinary Medicine has recently become aware of increased public visibility of the antiparasitic drug ivermectin after the announcement of a research article that described the effect of ivermectin on SARS-CoV-2 in a laboratory setting. The *Antiviral Research* pre-publication paper, "[The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro](https://www.sciencedirect.com/science/article/pii/S0166354220302011) (<https://www.sciencedirect.com/science/article/pii/S0166354220302011>)" (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), documents how SARS-CoV-2 (the virus that causes COVID-19) responded to ivermectin when exposed in a petri dish. This type of study is commonly used in the early stages of drug development. Ivermectin was not given to people or animals in this study. Additional testing is needed to determine whether ivermectin might be safe or effective to prevent or treat coronavirus or COVID-19.

Ivermectin tablets are approved for use in people for the treatment of some parasitic worms (intestinal strongyloidiasis and onchocerciasis) and ivermectin topical formulations **are approved for human use** by prescription-only for the treatment of external parasites such as headlice and skin conditions such as rosacea. Ivermectin is FDA-approved for use in animals for prevention of heartworm disease in some small animal species, and for treatment of certain internal and external parasites in various animal species.

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FDA is concerned about the health of consumers who may self-medicate by taking ivermectin products intended for animals, thinking they can be a substitute for ivermectin intended for humans. People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled. These animal drugs can cause serious harm in people. People should not take any form of ivermectin unless it has been prescribed to them by a licensed health care provider and is obtained through a legitimate source.

Ivermectin is an important part of a parasite control program for certain species and should only be given to animals for approved uses or as prescribed by a veterinarian in compliance with the requirements for extra-label drug use. Due to potentially elevated interest in ivermectin

following the new research, some products may not be available. If you are having difficulty locating a particular ivermectin product for your animal(s), the FDA recommends that you consult with your veterinarian.

The FDA has established a cross-agency task force dedicated to closely monitoring for fraudulent COVID-19 products that reaches out to major retailers to ask for their help in monitoring online marketplaces. Products that claim to prevent, diagnose, treat, or cure COVID-19 are subject to FDA investigation and potential enforcement action if they have not demonstrated safety and effectiveness for that intended use. The task force has already worked with retailers to remove dozens of these types of product listings online.

Please help us protect public health by alerting FDA of anyone claiming to have a product to prevent or cure COVID-19 and to help safeguard human and animal health by reporting any of these products to FDA-COVID-19-Fraudulent-Products@fda.hhs.gov (<mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov>) or 1-888-InfoFDA (1-888-463-6332).

We recognize this is a challenging time and urge you to continue practicing social distancing by sharing this information electronically.

Thank you for your support. Please stay safe and healthy.

Dr. Steven Solomon
Director of FDA's Center for Veterinary Medicine

Additional Information

[FAQ: COVID-19 and Ivermectin Intended for Animals \(/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals\)](#)

[Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 \(/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19\)](#)

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: Daily Roundup April 10, 2020

For Immediate Release:

April 10, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA recently issued an [emergency use authorization \(EUA\) for a blood purification system](/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-blood-purification-device-treat-covid-19) to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit with confirmed or imminent respiratory failure. The FDA issued the EUA to Terumo BCT Inc. and Marker Therapeutics AG for their Spectra Optia Apheresis System and Depuro D2000 Adsorption Cartridge devices.
- The FDA recently issued an [EUA to decontaminate compatible N95 or N95-equivalent respirators](/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-second-emergency-use-authorization-decontaminate-n95) for reuse by health care workers in hospital settings. The FDA issued the EUA to STERIS Corporation for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems using the STERIS N95 Decontamination Cycle (non-lumen cycle), which uses vaporized hydrogen peroxide. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S.
- The FDA issued a [guidance](/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-non-standard-ppe-practices-sterile-compounding-pharmacy-compounders-not) for immediate implementation for pharmacy compounders that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. PPE shortages have the potential to significantly impact the quality, purity and availability of drugs that are compounded for patients, including those in critical need. The guidance discusses how pharmacies may be able to preserve PPE if supplies are limited. Further, as a temporary measure to address the public health emergency posed by COVID-19, the agency is providing limited regulatory flexibility for compounders that cannot obtain sufficient supplies of PPE for sterile compounding, provided they adopt risk mitigation strategies as described in the guidance. FDA adopted this policy to help assure patient

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access to needed medicines and to reduce the risks of compounding when standard PPE are not available.

- Yesterday, the FDA and Federal Trade Commission issued a warning letter to one company for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller [warned \(/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/earthley-wellness-dba-modern-alternative-mama-llc-606525-04092020\)](/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/earthley-wellness-dba-modern-alternative-mama-llc-606525-04092020), Earthley Wellness DBA Modern Alternative Mama LLC., offers unapproved and misbranded herbal tinctures and herbal remedy products for the prevention or treatment of COVID-19. There are currently no approved preventatives or treatments for COVID-19. Consumers should not purchase or take any product to prevent or treat COVID-19 unless it is prescribed by their health care provider and acquired from a legitimate source.
- [FDA Voices: A Perspective on the FDA's COVID-19 Response \(/news-events/fda-voices/perspective-fdas-covid-19-response\)](/news-events/fda-voices/perspective-fdas-covid-19-response) by Mitch Zeller, director of the FDA's Center for Tobacco Products, was issued. It provides a perspective of the FDA's "all-hands-on-deck" approach to tackling this pandemic. The FDA is integral in the fight against the coronavirus, using science and innovative approaches to take a broad range of actions that advance our nation's response.
- [The FDA issued a Letter to Stakeholders \(/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans\)](/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans) advising people not use ivermectin intended for animals as a treatment for COVID-19 in humans. People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled. These animal drugs can cause serious harm in people. People should not take any form of ivermectin unless it has been prescribed to them by a licensed health care provider and is obtained through a legitimate source.
- Diagnostics update to date:
 - During the COVID-19 pandemic, the FDA has worked with more than 300 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
 - To date, 33 [emergency use authorizations \(/about-fda/page-not-found\)](/about-fda/page-not-found) have been issued for diagnostic tests.
 - The FDA has been notified that more than 170 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
 - The FDA also continues to keep its [COVID-19 Diagnostics FAQ \(/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2\)](/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) up to date.



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

- [Coronavirus Disease 2019 \(COVID-19\) \(/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19\)](/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)

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🔍 [More Press Announcements \(/news-events/newsroom/press-announcements\)](/news-events/newsroom/press-announcements)

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FAQ: COVID-19 and Ivermectin Intended for Animals

[Español \(/animal-veterinary/product-safety-information/preguntas-mas-comunes-el-covid-19-y-la-ivermectina-prevista-para-animales\).](#)

Q: Should I take ivermectin to prevent or treat COVID-19?

A: No. While there are approved uses for ivermectin in people and animals, it is not approved for the prevention or treatment of COVID-19. You should not take any medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source.

A recently released research article ([https://pdf.sciencedirectassets.com/271065/AIP/1-s2.0-S0166354220302011/main.pdf?X-Amz-Date=20200406T215853Z&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Signature=dfb8133954e6dd01ab978d9288f9036d2b49c25bb0995ff2ca061bc7ea3077fe&X-Amz-Credential=ASIAQ3PHCVTY32VGY2LR%2F20200406%2Fus-east-1%2Ffs3%2Faws4_request&type=client&tid=pr-2af71973-98c2-4d5f-954c-02bc9e60ea14&sid=45be74a6676495419c1ba842da478030ef40gxrrqa&pii=So166354220302011&X-Amz-SignedHeaders=host&X-Amz-Security-Token=IQoJb3JpZ2luX2VjEKX%2F%2F%2F%2F%2F%2F%2F%2F%2F%2FwEaCXVzLWVhc3QtMSJHMEUCIAI%2F6GH7Kt1FhbG5MZc%2BiCG7X1S1Amz-Expires=300&hash=24d1399e3e67515cfa0c8a128310fo4991eddo39c80bc29c8a30c84303aa5c67](https://pdf.sciencedirectassets.com/271065/AIP/1-s2.0-S0166354220302011/main.pdf?X-Amz-Date=20200406T215853Z&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Signature=dfb8133954e6dd01ab978d9288f9036d2b49c25bb0995ff2ca061bc7ea3077fe&X-Amz-Credential=ASIAQ3PHCVTY32VGY2LR%2F20200406%2Fus-east-1%2Ffs3%2Faws4_request&type=client&tid=pr-2af71973-98c2-4d5f-954c-02bc9e60ea14&sid=45be74a6676495419c1ba842da478030ef40gxrrqa&pii=So166354220302011&X-Amz-SignedHeaders=host&X-Amz-Security-Token=IQoJb3JpZ2luX2VjEKX%2F%2F%2F%2F%2F%2F%2F%2F%2F%2F%2FwEaCXVzLWVhc3QtMSJHMEUCIAI%2F6GH7Kt1FhbG5MZc%2BiCG7X1S1Amz-Expires=300&hash=24d1399e3e67515cfa0c8a128310fo4991eddo39c80bc29c8a30c84303aa5c67)) described the effect of ivermectin on SARS-CoV-2 in a laboratory setting. These types of laboratory studies are commonly used at an early stage of drug development. Additional testing is needed to determine whether ivermectin might be appropriate to prevent or treat coronavirus or COVID-19.

Q: Is there an emergency use authorization for ivermectin in the U.S. to prevent or treat coronavirus or COVID-19?

A: No. FDA has created a special emergency program for possible therapies, the [Coronavirus Treatment Acceleration Program \(/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap\)](#) (CTAP). It uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. We continue to support clinical trials that are testing new treatments for COVID so that we can gain valuable knowledge about their safety and effectiveness.

Q: What is ivermectin approved for in the U.S.?

A: Ivermectin tablets are approved for use in humans for the treatment of some parasitic worms (intestinal strongyloidiasis and onchocerciasis) and ivermectin topical formulations are approved for human use by prescription only for the treatment of external parasites such as headlice and for skin conditions such as rosacea.

Ivermectin is FDA-approved for use in animals for prevention of heartworm disease in some small animal species, and for treatment of certain internal and external parasites in various animal species. People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular species for which they are labeled. Using these products in humans could cause serious harm.

Q: Is there any danger to humans taking ivermectin?

A: There are approved uses for ivermectin in people and animals but it is not approved for the prevention or treatment of COVID-19. You should not take any medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source.

Some of the side-effects that may be associated with ivermectin include skin rash, nausea, vomiting, diarrhea, stomach pain, facial or limb swelling, neurologic adverse events (dizziness, seizures, confusion), sudden drop in blood pressure, severe skin rash potentially requiring hospitalization and liver injury (hepatitis). Laboratory test abnormalities include decrease in white cell count and elevated liver tests. 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 for us to determine whether ivermectin is safe and effective in treating or preventing COVID-19.

Q: What should I do if the ivermectin products I purchase for use in my animals are not available at my typical retailer?

A: Ivermectin is an important part of a parasite control program for certain species and should only be given to animals for approved uses or as prescribed by a veterinarian in compliance with the requirements for extra-label drug use. Due to potentially elevated interest in ivermectin following the new research, some products may not be available. If you are having difficulty locating a particular ivermectin product for your animal(s), the FDA recommends that you consult with your veterinarian.

Q: What is the FDA doing to protect people from fraudulent COVID-19 products?



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A: We have established a cross-agency task force dedicated to closely monitoring for fraudulent COVID-19 products. We have reached out to major retailers to ask for their help in monitoring online marketplaces for fraudulent COVID-19 products. Products sold are subject to FDA investigation and potential enforcement action if they claim to prevent, diagnose, treat, or cure COVID-19 and have not demonstrated safety and effectiveness for that intended use. The task force has already worked with retailers to remove dozens of these types of product listings online.

The FDA and the Federal Trade Commission (FTC) issue warning letters to companies that violate federal law and pose significant risks to patient health by selling unapproved products with fraudulent claims to treat or prevent COVID-19. [View the warning letters \(/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products#Warning Letter Table\)](#) for more information.

Additional Information

[FDA Letter to Stakeholders: Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans \(/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans\)](#).

[Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 \(/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19\)](#).

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19



[Español \(/consumers/articulos-en-espanol/por-que-no-debe-utilizar-ivermectina-para-tratar-o-prevenir-el-covid-19\)](#)

[Português \(/consumers/consumer-updates/por-que-voce-nao-deve-usar-ivermectina-para-tratar-ou-prevenir-covid-19\)](#)

[中文 \(/consumers/consumer-updates/weishenmebuyinggaishiyongyiweijunsuzhiliaohuoyufang2019xinguanfeiyang\)](#)

[Tagalog \(/consumers/consumer-updates/bakit-hindi-ka-dapat-gumamit-ng-ivermectin-upang-gamutin-o-maiwasan-ang-covid-19\)](#)

[Tiếng Việt \(/consumers/consumer-updates/tai-sao-ban-khong-nen-su-dung-ivermectin-de-dieu-tri-hoac-ngan-ngua-covid-19\)](#)

[한국어 \(/consumers/consumer-updates/kobideu-19-covid-19leul-chilyohago-yebanghagi-wihayeo-ibeomegtineul-sayonghaji-malaya-haneun-iyu\)](#)

COVID-19. We've been living with it for what sometimes seems like forever. Given the number of deaths that have occurred from the disease, it's perhaps not surprising that some consumers are turning to drugs not approved or authorized by the Food and Drug Administration (FDA).

One of the FDA's jobs is to carefully evaluate the scientific data on a drug to be sure that it is both safe and effective for a particular use. In some instances, it can be highly dangerous to use a medicine for the prevention or treatment of COVID-19 that has not been approved by or has not received emergency use authorization from the FDA.

There seems to be a growing interest in a drug called ivermectin for the prevention or treatment of COVID-19 in humans. Certain animal formulations of ivermectin such as pour-on, injectable, paste, and "drench," are approved in the U.S. to treat or prevent parasites in animals. For humans, ivermectin tablets are approved at very specific doses to treat some parasitic worms, and there are topical (on the skin) formulations for head lice and skin conditions like rosacea.

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However, the FDA has received multiple reports of patients who have required medical attention, including hospitalization, after self-medicating with ivermectin intended for livestock.

Here's What You Need to Know about Ivermectin

- The FDA has not authorized or approved ivermectin for use in preventing or treating COVID-19 in humans or animals. Ivermectin is approved for human use to treat infections caused by some parasitic worms and head lice and skin conditions like rosacea.
- Currently available data do not show ivermectin is effective against COVID-19. [Clinical trials \(https://www.clinicaltrials.gov/ct2/results?cond=COVID-19&term=ivermectin&cntry=&state=&city=&dist=&Search=Search\)](https://www.clinicaltrials.gov/ct2/results?cond=COVID-19&term=ivermectin&cntry=&state=&city=&dist=&Search=Search) assessing ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing.
- Taking large doses of ivermectin is dangerous.
- If your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed.
- Never use medications intended for animals on yourself or other people. Animal ivermectin products are very different from those approved for humans. Use of animal ivermectin for the prevention or treatment of COVID-19 in humans is dangerous.

What is Ivermectin and How is it Used?

Ivermectin tablets are approved by the FDA to treat people with intestinal strongyloidiasis and onchocerciasis, two conditions caused by parasitic worms. In addition, some topical forms of ivermectin are approved to treat external parasites like head lice and for skin conditions such as rosacea.

Some forms of animal ivermectin are approved to prevent heartworm disease and treat certain internal and external parasites. It's important to note that these products are different from the ones for people, and safe only when used in animals as prescribed.

When Can Taking Ivermectin Be Unsafe?

The FDA has not authorized or approved ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not been shown to be safe or effective for these indications.

There's a lot of misinformation around, and you may have heard that it's okay to take large doses of ivermectin. It is not okay.

Even the levels of ivermectin for approved human uses can interact with other medications, like blood-thinners. You can also overdose on ivermectin, which can cause nausea, vomiting, diarrhea, hypotension (low blood pressure), allergic reactions (itching and hives), dizziness, ataxia (problems with balance), seizures, coma and even death.

Ivermectin Products for Animals Are Different from Ivermectin Products for People

For one thing, animal drugs are often highly concentrated because they are used for large animals like horses and cows, which weigh a lot more than we do—a ton or more. Such high doses can be highly toxic in humans. Moreover, the FDA reviews drugs not just for safety and effectiveness of the active ingredients, but also for the inactive ingredients. Many inactive ingredients found in products for animals aren't evaluated for use in people. Or they are included in much greater quantity than those used in people. In some cases, we don't know how those inactive ingredients will affect how ivermectin is absorbed in the human body.

Options for Preventing and Treating COVID-19

The most effective ways to limit the spread of COVID-19 (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>) include getting a COVID-19 vaccine when it is available to you and following current CDC guidance.

Talk to your health care provider about available COVID-19 vaccines and treatment options. Your provider can help determine the best option for you, based on your health history.