

What the FDA wants doctors to tell patients asking for ivermectin

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Ivermectin, an anti-parasitic drug often used in animals, has seen a steep rise in prescriptions as patients seek out alternative treatments for COVID-19. If a patient insists on this drug, infectious disease expert John Farley, MD, MPH, has the following advice for doctors: tell that patient to get vaccinated.

“If they're infected and qualify for monoclonal antibodies, they should be treated,” said Dr. Farley, director of the Food and Drug Administration (FDA) Office of Infectious Diseases in the Center for Drug Evaluation and Research.

The FDA has not approved or authorized ivermectin drug for COVID-19, and other federal agencies have warned against its use for preventing and treating the virus. In an episode of “AMA COVID-19 Update,” Dr. Farley discussed the drug’s safety concerns, its potential side effects and the important role of physicians in guiding the unvaccinated to better choices.

The AMA has joined other organizations in opposing the ordering, prescribing or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.

Little evidence supporting ivermectin

Results from small clinical trials touting its benefits has fueled patient interest. However, many of these trials took place in other countries, without any FDA oversight.

“We actually have no way of confirming whether the results reported in those trials are real or not,” Dr. Farley said. Other clinical trials have shown no benefit for ivermectin.

People who choose ivermectin over vaccination could be making a tragic mistake, he cautioned. Physicians should leverage their status as a trusted source to guide patients to another solution.

“If they're sitting in your exam room, even if they're pushing back and giving you a hard time, they trust your recommendations. I would encourage them to get vaccinated for prevention,” said Dr. Farley. Any patient with COVID-19 who is in a high-risk group should get treated with a monoclonal antibody to help stay out of the hospital.

Not always intended for humans

While some ivermectin products are meant for humans, others are specifically formulated for animal or veterinary use. The problem with humans taking drugs intended for animals is those drug formulations often contain ingredients that would be safe for a horse or a cow but not for a human, said Dr. Farley.

The FDA has identified multiple reports of patients who tried to self-medicate with ivermectin products intended for livestock and were subsequently hospitalized.

Some oral formulations have been approved by FDA to treat people with parasitic worms. “It’s a valuable drug, particularly in international settings,” Dr. Farley said. Generally, it’s given as a single-dose treatment and repeated only at recommended intervals.

“We actually don’t have data about the safety of taking ivermectin every day for a long period of time,” he added.

The drug can cause stomach problems, skin rash and itching, and nervous system problems such as dizziness and tremors.

COVID-19 treatment trials underway

Everyone wants a pill to treat COVID-19. Clinical trials are underway to examine by-mouth drugs to treat the deadly illness. “That’s a very high priority for the government. We need to wait for the results of those trials to know if one of those treatments shows benefit,” said Dr. Farley.

If the trial data is convincing enough, the federal government will work as hard as it can to make that treatment available and provide physicians information they need to maximize benefit and minimize risk, he emphasized.

Patients infected with COVID-19 and at low risk for disease progression who insist on ivermectin should join a clinical trial. This way, they'd get treated with a safe formulation of the drug, at the right dose, said Dr. Farley. Patients can find clinical trials available with contact information at clinicaltrials.gov.

Get the latest news on the COVID-19 pandemic, vaccines and variants, and more reliable information directly from experts and physician leaders with the "AMA COVID-19 Update."

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