

NC Department of Health and Human Services

SUMMARY



Due to a recent spike in prescriptions for **ivermectin** (an antiparasitic drug), related poison control calls and emergency room visits, NCDHHS is informing all providers that **ivermectin is neither approved nor authorized by the FDA to treat or prevent COVID-19**. The National Institutes of Health (NIH) has determined there is insufficient data to recommend for or against ivermectin for treatment of COVID-19. **Exercise caution when prescribing this drug outside of authorized treatment avenues.**

We need your help. Please educate your patients about the risks of using ivermectin without a prescription and the potential risks of use for the prevention or treatment of COVID-19. Talking points for providers are included in this communication. Further information is available in the CDC Health Advisory on Ivermectin Use to Prevent or Treat COVID-19.

September 14, 2021

Concerns with Ivermectin Use for COVID-19

NCDHHS appreciates all North Carolina providers and their efforts to keep patients and communities safe during the COVID-19 pandemic. We are aware of growing public interest for the antiparasitic drug ivermectin as a COVID-19 treatment option.

Ivermectin tablets are approved for use in humans for the treatment of some parasitic worms (intestinal strongyloidiasis and onchocerciasis). Some topical formulations are approved for the treatment of headlice and skin conditions such as rosacea. Most notably, ivermectin is approved for use in animals for prevention of heartworm disease and for treatment of certain parasites.

While we recognize that off-label prescribing is a common practice, ivermectin is not currently recommended for prevention or treatment of COVID-19 and is not a substitute for a COVID-19 vaccine or approved treatments for the disease. **Prescribers should exercise caution if prescribing a drug outside FDA authorization or approval.**

We have received reports of an increase in prescriptions for ivermectin, as well as poison control calls and emergency department visits connected to ivermectin. Multiple North Carolina payors, including Medicaid, are putting Prior Approval processes in place due to rising prescriptions. These policies are not meant to prevent ivermectin prescriptions for approved indications or impede clinical trial uses.

We are asking all providers to educate patients about the risks and dangers of using ivermectin without a prescription, ingesting ivermectin formulations that are meant for external use, or taking ivermectin-containing products meant for animal use.

Talking points for Clinicians and Public Health Practitioners:

 The <u>FDA has not authorized</u> or approved ivermectin for preventing or treating COVID-19 in humans or animals.

- Current data are inconclusive whether ivermectin is effective against prevention or treatment of COVID-19. <u>Clinical trials</u> are in progress to determine what clinical benefit, if any, ivermectin may offer in treating COVID-19.
- Taking large doses of ivermectin, even if prescribed, can be dangerous.
- 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.
- Signs and symptoms of ivermectin toxicity include gastrointestinal effects (nausea, vomiting, abdominal pain, and diarrhea), headache, blurred vision, dizziness, tachycardia, hypotension, visual hallucinations, altered mental status, confusion, loss of coordination and balance, central nervous system depression, and seizures. (See page 3 of the CDC Health Advisory on Ivermectin Use to Prevent or Treat COVID-19.) If patients report they have taken ivermectin and are experiencing symptoms, advise them to immediately seek medical treatment and to call the North Carolina Poison Control Center (NCPCC) hotline (1-800-222-1222).
- Monoclonal antibodies are authorized by the FDA and recommended by the NIH for treatment and post-exposure prevention of COVID
- COVID-19 vaccination is approved by FDA and is the safest and most effective way to prevent getting sick and protect against severe disease and death from SARS-CoV-2, the virus that causes COVID-19, including the Delta variant.
- Patients, especially those who are unvaccinated, should continue practicing common public health protocols, including social distancing, washing hands, and wearing a mask.

Ivermectin for COVID-19 Guidance

- The NIH has determined that there is insufficient data to recommend for or against ivermectin for treatment of COVID-19.
- On August 26, 2021, CDC issued a <u>CDC Health Advisory on Ivermectin Use to Prevent or Treat</u> COVID-19.
- The FDA has issued a statement on Why You Should Not Use Ivermectin to Treat or Prevent COVID-19.
- Prescribers and pharmacists can check with their licensing agency about expectations regarding prescribing or filling prescriptions for ivermectin.
 - www.ncmedboard.org
 - o www.ncbon.com
 - o www.ncbop.org
- Complaints can also be made to NC DHHS using the <u>covidcomplaints@dhhs.nc.gov</u> address

Thank you for your continued vigilance,

Elizabeth Cuervo Tilson, MD, MPH

State Health Director, Chief Medical Officer

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