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Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19

Summary

Ivermectin is a U.S. Food and Drug Administration (FDA)-approved prescription medication used to treat certain infections caused by internal and external parasites. When used as prescribed for approved indications, it is generally safe and well tolerated. <u>Ivermectin is not authorized or approved by FDA for prevention or treatment of COVID-19.</u>

During the COVID-19 pandemic, ivermectin dispensing by retail pharmacies has increased, as has use of veterinary formulations available over the counter but not intended for human use. FDA has cautioned about the potential risks of use for prevention or treatment of COVID-19. Adverse effects associated with ivermectin misuse and overdose are increasing, as shown by a rise in calls to poison control centers reporting overdoses and more people experiencing adverse effects.

- A recent study examining trends in ivermectin dispensing from outpatient retail pharmacies in the United States during the COVID-19 pandemic showed an increase from an average of 3,600 prescriptions per week at the pre-pandemic baseline (March 16, 2019–March 13, 2020) to a peak of 39,000 prescriptions in the week ending on January 8, 2021. Since early July 2021, outpatient ivermectin dispensing has again begun to rapidly increase, reaching more than 88,000 prescriptions in the week ending August 13, 2021. This represents a 24-fold increase from the pre-pandemic baseline.
- In 2021, poison control centers across the U.S. received a three-fold increase in the number of
 calls for human exposures to ivermectin in January 2021 compared to the pre-pandemic baseline.
 In July 2021, ivermectin calls have continued to sharply increase, to a five-fold increase from
 baseline. These reports are also associated with increased frequency of adverse effects and
 emergency department/hospital visits.

Recommendations for Clinicians and Public Health Practitioners

- Be aware that ivermectin is not currently authorized or approved by FDA for treatment of COVID-19. NIH has also determined that there are currently insufficient data to recommend ivermectin for treatment of COVID-19.
- Educate patients about the risks of using ivermectin without a prescription, or ingesting ivermectin formulations that are meant for external use or ivermectin-containing products formulated for veterinary use.
- Advise patients to immediately seek medical treatment if they have taken any ivermectin or
 ivermectin-containing products and are experiencing symptoms. 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. Ivermectin may increase sedative effects of other medications such as
 benzodiazepines and barbiturates. Call the poison control center hotline (1-800-222-1222) for
 medical management advice.
- Educate patients and the public to get vaccinated against COVID-19. COVID-19 vaccination is safe and the most effective means to prevent infection and protect against severe disease and death from SARS-CoV-2, the virus that causes COVID-19, including the Delta variant.
- Educate patients and the public to use COVID-19 prevention measures including wearing masks in indoor public places, physical distancing by staying at least six feet from other people who don't live in the same household, avoiding crowds and poorly ventilated spaces, and frequent handwashing and use of hand sanitizer that contains at least 60 percent alcohol.

Resources for Additional Information

- NIH COVID-19 Treatment Ivermectin Guidelines
 https://www.covid19treatmentquidelines.nih.gov/therapies/antiviral-therapy/ivermectin/
- <u>FDA Consumer Alert on Use of Ivermectin to Treat or Prevent COVID-19</u>
 <u>https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19</u>
- FDA MedWatch Adverse Event Reporting program
 https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
- CDC Coronavirus (COVID-19) website https://www.coronavirus.gov/
- American Association of Poison Control Centers https://www.aapcc.org/
- Press Release: American College of Medical Toxicology Reports Data on Adverse Effects and Toxicity from Unapproved Use of Ivermectin for the Prevention or Treatment of COVID-19 https://www.acmt.net/ Library/Press Releases/ACMT Press Release Ivermectin.pdf

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