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013. Ivermectin Associated Adverse Events in the Treatment and Prophylaxis of COVID-19 Reported to the FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance

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Background: Since the beginning of the COVID-19 pandemic, there has been an interest in repurposing currently available pharmaceuticals, such as ivermectin.

Methods: This is a prospective case series of adverse events (AEs) submitted to the FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance Project between 11/23/20 and 8/30/21. FACT is an active surveillance project with 15 participating medical centers focusing on identifying possible AEs related to any medication or substance administered with intent to treat or prevent COVID-19 infection. Cases were included if the implicated substance of the AE was identified as ivermectin.

Results: A total of 42 cases of self-medication with ivermectin were reported to the FACT Pharmacovigilance Project during the study period. The median age was 53 years [range 39-65]; 48% were female. Selfmedication with veterinary paste and injectable formulations were the most cited sources of ivermectin. Doses ranged from 12 mg to 1360 mg. Patients reported using ivermectin for prophylaxis (60%), for treatment of documented COVID-19 (21%), and for treatment of symptoms of undocumented COVID-19 (14%). Thirty patients (71%) presented to emergency departments and ten patients (24%) were admitted to the hospital. Neurological toxicity was the most frequent finding, ranging from headache (10%), numbness (5%), weakness (5%), tremors (7%), dizziness (21%), to hallucinations (5%), altered mental status (29%), confusion (21%), visual disturbances and visual hallucinations (12%) and seizures (7%). Gastrointestinal symptoms (24%) were also reported. Three patients who took a veterinary parenteral preparation containing propylene glycol (50-60%) orally developed lactic acidosis, hypotension and tachycardia.

Conclusion: Ivermectin use for the attempted treatment and prophylaxis of COVID-19, despite its lack of documented efficacy, has the potential for serious adverse health effects. This is especially true when patients are self-treating with this medication and when they are using formulations with large doses for multiple days intended for use in large animals.