

Safety of Ivermectin

Standard doses of ivermectin (0.2 mg/kg x 1–2 days) have a nearly unparalleled safety profile historically among medicines as evidenced by the following findings:

- WHO Guidelines for Scabies: "the majority of side effects are minor and transient"
- Prof. Jacques Descotes, Toxicologist and Expert on Safety of Ivermectin: "severe adverse events are unequivocally and exceedingly rare"
- LiverTox Database: Not considered toxic to the liver
- Nephrotox Database: Not considered toxic to the kidney
- PneumoTox: Not considered toxic to the lungs

Safety of High Dose Ivermectin

In COVID-19, particularly with regard to the emerging variants of concern, viral loads are higher and viral replication is thought to be prolonged. Given that ivermectin has <u>demonstrated a strong dose-response relationship</u> in terms of viral clearance, higher doses have not only been required, but have demonstrated clinical efficacy. Below are hyperlinked references to numerous studies demonstrating the wide safety profile of high dose ivermectin in COVID and other diseases.

COVID-19 Studies

- 1) Randomized controlled trial of ivermectin in COVID using 0.6mg/kg x 5 days reported no differences in side effects.
- 2) Randomized controlled trial, with 3 arms; one arm treated with 1.2 mg/kg x 5 days, and another treated with 0.6mg/kg x 5 days with no differences in side effects.
- 3) A report by the State Health Minister on 3,000 patients in La Pampa, Argentina who were part of a "test and treat" program were given 0.6 mg/kg daily x 5 days. Liver function tests and significant side effects were closely monitored and none were reported.
- 4) A report by the Health Minister in Misiones, Argentina, also using 0.6 mg/kg x 5 days with no significant adverse events reported.

Malaria Studies

- 1) <u>Ivermectin alone was safe and well-tolerated</u> in macaques with repeated doses at 0.3 and 1.2 mg/kg x 7 days, with no signs of neurological, gastroenterological, or hematological complications.
- 2) Study of "Efficacy and Safety of High dose ivermectin for Reducing Malaria Transmission" compared 0, 0.3 and 0.6 mg/kg x 3 days and found no differences in side effects.



Healthy Volunteers

1) Report of a group of healthy adult subjects given up to 10x standard dose, either 2-4x the standard dose three times a week or 6–10x standard dose once and found the doses generally well tolerated.

Systematic Reviews

- A systematic review and meta-analysis of high dose ivermectin found no difference in side effects between dose of up to 0.4 mg/kg and higher doses (up to 0.8 mg/kg doses every 3 months.
- 2) A comprehensive review of 350 articles by the famous French toxicologist Jacques Descotes was presented in early 2021. In this document, he states,
 - a. "Based on all the data presented above, the author of this report believes it is fair to say that ivermectin did not directly induce an excess of deaths in treated groups of human subjects. Statements, past or present, that ivermectin can kill patients, are therefore considered to be misleading as they do not take into account all the medical information that has been accumulated over the last decades."
 - b. "Only very few cases of accidental human overdose have been reported despite the wide availability of ivermectin as a veterinary and human medicine [Hall et al., 1985;Graeme et al., 2000; Deraemecker et al., 2014; Goossens et al., 2014]. Usually, moderate neurotoxic manifestations with rapid recovery after unspecific supportive measures were the predominating course of events. No accidental overdose including in infants and young children had a lethal outcome."

Case Series

A case series of 3 children with relapsed leukemia treated with high dose (1.0 mg/kg) ivermectin daily for between 2 weeks and 6 months reported no significant adverse events.

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