

CMA's Response to TGA's New Ashwagandha (*Withania somnifera*) Gastrointestinal / Liver Reports

The Therapeutic Goods Administration (TGA) has published a safety advisory regarding emerging reports of gastrointestinal symptoms associated with the ingredient *Withania somnifera* (also known as Ashwagandha). Some consumers experience mild gastrointestinal symptoms to herbal ingredients including Withania. The TGA safety advisory reports that *Withania somnifera* has caused more severe gastrointestinal symptoms such as nausea, vomiting or diarrhoea in some cases and in very rare cases, possible liver injury.

The root of *Withania somnifera* has been traditionally used in Ayurvedic medicine for centuries for a range of health benefits, and has gained wider use within traditional Western herbal medicine for supporting resilience during stress, with scientific studies providing support for this use.¹ Medicines containing *Withania somnifera* including both the root and/or the leaves or other plant parts have been permitted for use in Australia for over 30 years, for which there are around 370 products on the Australian Register of Therapeutic Goods.

Complementary Medicines Australia (CMA) and our members are aware of national and international safety signals about the ingredient as part of regular monitoring activities and are continuing to investigate these concerns as part of our mission to promote high quality products and appropriate industry regulation.

In 2020, a major review was published of twenty randomised controlled trials examining the safety and efficacy of *Withania somnifera* root with over a thousand participants.² In fifteen of these trials no treatment related adverse events were reported. A small number of people in the other trials reported mild, mainly transient symptoms. The most common, experienced by less than 5% of people included stomach discomfort and loose stools, however with no serious adverse events.²

While several reports of liver injury within medical literature have been published more recently, a proportion of the individuals concerned had serious pre-existing liver conditions.³ In 2023, a review examined three studies which measured liver enzymes and found they remained within the healthy range⁴ and in 2021 a systematic review of 12 studies trialling Withania extracts in healthy people found no serious health concerns.⁵

CMA emphasise the importance of information within the TGA safety advisory of not purchasing overseas herbal products that do not contain an 'AUST L' or 'AUST R' number on the label. Overseas products are not subject to the same strict manufacturing standards and regulatory expectations as Australian 'AUST L and AUST R' products.

CMA recommends always reading the label and directions for use and not exceeding the recommended dose of herbal medicines. Anyone experiencing unusual symptoms to any medication should consult their healthcare professional and report the issue to the company selling the product.

¹ Akhgarjand, C., Asoudeh, F., Bagheri, A., Kalantar, Z., Vahabi, Z., Shab-bidar, S., Rezvani, H., & Djafarian, K. (2022). Does Ashwagandha supplementation have a beneficial effect on the

management of anxiety and stress? A systematic review and meta-analysis of randomized controlled trials. *Phytotherapy Research*, 36(11), 4115–4124. <https://doi.org/10.1002/ptr.7598>

² Tandon, N., & Yadav, S. S. (2020). Safety and clinical effectiveness of *Withania Somnifera* (Linn.) Dunal root in human ailments. *Journal of Ethnopharmacology*, 255, 112768-. <https://doi.org/10.1016/j.jep.2020.112768>

³ Philips CA, Valsan A, Theruvath AH, Ravindran R, Oommen TT, Rajesh S, Bishnu S, Augustine P; Liver Research Club India. Ashwagandha-induced liver injury-A case series from India and literature review. *Hepatol Commun*. 2023 Sep 27;7(10):e0270. doi: 10.1097/HC9.0000000000000270.

⁴ Gómez Afonso A, Fernandez-Lazaro D, Adams DP, Monserdà-Vilaró A, Fernandez-Lazaro CI. Effects of *Withania somnifera* (Ashwagandha) on Hematological and Biochemical Markers, Hormonal Behavior, and Oxidant Response in Healthy Adults: A Systematic Review. *Curr Nutr Rep*. 2023 Sep;12(3):465-477. doi: 10.1007/s13668-023-00481-0.

⁵ Bonilla DA, Moreno Y, Gho C, Petro JL, Odriozola-Martínez A, Kreider RB. Effects of Ashwagandha (*Withania somnifera*) on Physical Performance: Systematic Review and Bayesian Meta-Analysis. *J Funct Morphol Kinesiol*. 2021 Feb 11;6(1):20. doi: 10.3390/jfmk6010020.