CRITICAL RECALL

Nature's Sunshine Andrographis

Batch/Lot Number: 2212 **Expiry Date(s): 10/28**

ARTG: 302367 Nature's Sunshine Andrographis

TGA Ref: RC-2026-RN-00869-1

Nature's Sunshine, following agreement with the Therapeutic Goods Administration (TGA), is conducting a recall of all batches that are still within expiry for the above listed medicine Andrographis. The product has been supplied to your organisation.

WHAT IS THE PROBLEM?	• Since 2019, listed medicines containing *Andrographis paniculata* (Andrographis) for supply in Australia have been required to carry a label warning about the risk of allergic reactions including severe reactions such as anaphylaxis. • However, despite these warnings, the TGA has continued to receive a sustained high number of reports of anaphylaxis associated with Andrographis-containing listed medicines, which are considered low-risk medicines. • Andrographis has now been removed from the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026*. This means the ingredient is no longer available for use in new listed (low risk) medicines for supply in Australia. • Further information on this decision is available at https://www.tga.gov.au/news/news-articles/andrographis-removed-listed-medicines-framework-because-allergy-risk
WHAT IS THE HAZARD/RISK?	• Anaphylaxis is the most severe type of allergic reaction and is a medical emergency. • It requires immediate treatment with adrenaline (epinephrine). Delayed treatment can be life-threatening. • Andrographis-related anaphylaxis reactions are unpredictable and can happen the first time someone takes it, or after taking it previously without any issue.

WHAT SHOULD YOU DO?	• Inspect your stock **immediately** and quarantine all stock of Andrographis on hand to prevent further use or distribution. • **Complete the Customer Response Form, even if you do not have any affected stock** • **Submit your form via MyRener Recall Returns Upload. The Customer Service Team at Rener Health Products will respond with further instructions. All credits will be processed once returned stock has been assessed. A credit will be placed on your Rener Health Products account.** • Provide distribution details – If you have supplied this batch to other retailers or businesses, please complete the attached **Customer Distribution List Template and submit via the MyRener Recall Returns Upload** • Notify your customers – Forward the attached Recall Letter, Public Recall Notice and Customer Response Form to any retailers or businesses you have supplied. • Ensure relevant staff members are informed of this recall. • If you have supplied or transferred any of the above product to another facility or organisation, provide that facility with a copy of this letter immediately. • Place this letter in a prominent position for at least one month. • Retailers are recommended to place the 'Public Notice' attached to this letter in their storefront to alert consumers about the recall. **Consumers** • Consumers are advised that if they have the above product, to not use it. • Consumers can return the product to the place of purchase or contact Nature's Sunshine on **1800 687 577**or **conatct@nspaust.com.au** to arrange the return of product for a refund. If someone is suspected of having anaphylaxis, call for emergency medical help immediately by dialling '000'.
CONTACT INFORMATION	For questions regarding this letter, please contact: Adele Ghraiche 02 9894 0111 / 1800 687 577 adele@nspaust.com.au

Thank you for your assistance in helping us to manage this recall.

Adele Ghraiche | Technical & Regulatory Affairs Manager

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