Date: 13th October 2026

CRITICAL RECALL:
Immunitone Plus Designs for Health

Batch Numbers:
All batches within expiry (40242, 40900, 42137, 42574, 43680, 45550)
Expiry Dates: November 2026 to March 2029

ARTG: AUST L 383995 Immunitone Plus
TGA Ref: RC-2026-RN-00811-1
Sponsor Ref: IMP090-AU

Dear Customer,

Designs for Health Pty Ltd, 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 Immunitone Plus. 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 *High-moderate risk changes to permissible ingredients – Andrographis paniculata 2026 | Therapeutic Goods Administration (TGA)*
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?	All distributors, retailers and practitioners: 1 Inspect your stock **immediately** and quarantine all stock of Immunitone Plus (AUST L 383995) on hand to prevent further use or distribution. 2 Ensure relevant staff members are informed of this recall. 3 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. 4 Place this letter in a prominent position for at least one month. 5 Retailers are recommended to place the 'Public Notice' attached to this letter in their storefront to alert consumers about the recall. **If you purchased from Rener Health Products:** 6 Complete the attached Customer Response Form immediately *even if you do not have any affected stock* and return it via MyRener Recall Returns Upload 7 Rener Health Products' customer Service Team will respond to your form with instructions to return any stock. 8 Following receipt of returned stock, we will arrange a credit on your account 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 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: Sophie Cutler at Designs for Health Pty Ltd recalls@designsforhealth.com.au | +61 2 9136 6266

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



Lea McIntyre
Managing Director