

1. WHAT IS THE ISSUE?

Please note: this is <u>not</u> a quality issue. This issue relates to labelling non-compliance as a result of newly published TGA guidelines. It has come to our attention that L-Tryptophan is now included in the newest S4 Schedule, published by TGA on 19th January 2024.

A Schedule 4 substance is a 'Prescription only medicine', which is defined as: "Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription."

Tryptophan is now regulated under this schedule 'for human therapeutic use **except** in preparations labelled with a recommended daily dose of 100 mg or less of Tryptophan'.

2. WILL THE PRODUCT NEED TO BE REMOVED? YES

- a. Please immediately remove product from sale online.
- b. Ensure to remove all images and references on <u>all</u> websites

3. How will I return the product?

Please contact your distributor to arrange return and credit.

4. WILL THE PRODUCT BE REINSTATED?

We are seeking further clarification on whether this product is still able to be sold with revised label complying with new guidelines.

5. COMPLIANCE

HealthWise wish to ensure that all our valued stockists are not inadvertently compromised by supplying product that is non-compliant.

Please be aware that it would be a breach of the TGA regulations to supply this product with the current label, effective immediately.

6. YOUR CONFIRMATION

Please confirm by email that you have actioned this request and removed all HealthWise Tryptophan from sale – online and retail. Email: admin@krpan.com

We thank you for your support of our HealthWise range appreciate your patience and understanding while we navigate these new protocols. The HealthWise® Team Email: admin@krpan.com