

24 July 2018

Dear Pharmacist

URGENT MEDICINE RECALL

CONSUMER LEVEL

Product	Batch/Lot	Expiry	Pharmacode
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	Oct 2020	2207842
Supplied after 28 March 2018 under Section 29 of the Medicines Act 1981			

Issue:

Pharmacy Retailing NZ Limited t/a Healthcare Logistics as New Zealand sponsor is recalling the above lot of Worldwide Labs Melatonin Tabs 3mg 90s from patients, pharmacies, hospital pharmacies and wholesalers. This product is supplied under section 29 of the Medicines Act 1981. This recall has been initiated because a small metal foreign object thought to be from a wire brush strand was found in one tablet from this batch. This may cause irritation and discomfort if consumed.

Actions:

- Please immediately inspect your stock, and quarantine all units of this lot to prevent further use. This includes any stock holdings in hospital wards and other locations if applicable.
- Please immediately contact all your patients that you have dispensed this lot to and request that they return any unused tablets from this lot to your pharmacy. If you are unable to identify the lot number from your records then contact all patients that you have dispensed Worldwide Labs Melatonin Tabs 3mg 90s since 28th March 2018. We have produced and enclosed a patient information leaflet you may find useful when explaining to patients the nature of the issue. You may wish to post this to customers you are unable to contact.
- Please return your affected stock to your supplier for lodgement of claim.
- Please complete the attached Pharmacy Stock Acknowledgement Form for your pharmacy stockholdings even if you no longer have any of the affected lot in your possession. Please return the Stock Acknowledgement Form to us either by free fax to 0508 982 520 or email to recall@healthcarelogistics.co.nz as soon as possible.
- Please use the attached Patient Stock Acknowledgement Form for patients that are required to return this lot to your pharmacy.
- Please return the Patient Stock Acknowledgement Form to us once these details are available either by free fax to 0508 982 520 or email to recall@healthcarelogistics.co.nz as soon as possible.
- Please return the affected stock from your patients to your supplier for lodgement of claim. Please ensure no patient identification details are on the stock returns.
- If you have supplied or transferred any potentially affected product to another facility or organisation, please provide contact details of that organisation in the Stock Acknowledgement Form.
- Please retain this letter in a prominent position for one month.

- There is adequate stock available at wholesalers to replace any returns.
- A consumer level recall notice will also be placed in daily newspapers. When a patient returns stock, please supply the patient with the same number of tablets as has been returned. This is permitted without the need for a new prescription.

Should you have any questions about this recall, please do not hesitate to contact us on the following details:

Phone: 0508 229 477

Fax: 0508 982 520

Email: recall@healthcarelogistics.co.nz

This action has been carried out following consultation with Medsafe, Ministry of Health.

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.

Yours sincerely,



Matt Taylor

Quality Systems Manager

Healthcare Logistics

Stock Acknowledgement Form – Pharmacy Stockholding

Product	Lot	Expiry	Pharmacode
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	31 October 2020	2207842

Supplied under Section 29 of the Medicines Act 1981

Confirmation of Melatonin Tablets to be recalled

Product	Lot	Expiry	Quantity (full bottles)	Part bottles
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	31 October 2020		

Purchased from (Wholesaler): _____

Any other relevant details: _____

I confirm that I have checked my dispensing records and contacted any patients affected by this recall.

From:

First Name: _____ **Surname:** _____

Position: _____

Institution: _____

Address: _____

Telephone Number: _____ **Fax:** _____

E-mail: _____

Signed: _____ **Date:** ____/____/____

Please return to Healthcare Logistics either by free fax on 0508 982 520, or e-mail:
recall@healthcarelogistics.co.nz **as soon as possible**

Stock Acknowledgement Form – Patient Returns

Product	Lot	Expiry	Pharmacode
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	OCT2020	2207842

Supplied under Section 29 of the Medicines Act 1981

Use this table to detail the number of bottles to be returned from patients that have returned this lot:

Product	Lot	Expiry	Number of Patients Contacted	Number of Bottles to return (including part bottles)
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	31 October 2020		

Please ensure you remove patient identification details

From:

First Name: _____ **Surname:** _____

Position: _____

Institution: _____

Address: _____

Telephone Number: _____ **Fax:** _____

E-mail: _____

Signed: _____ **Date:** ____/____/____

Please return to Healthcare Logistics either by free fax on 0508 982 520, or e-mail:
recall@healthcarelogistics.co.nz **as soon as possible**

Patient Information Letter

Product	Lot	Expiry
Worldwide Labs Melatonin Tabs 3mg 90s	P1710056	OCT2020
Supplied after 28 March 2018 under Section 29 of the Medicines Act 1981		

24 July 2018

Important information for patients prescribed Worldwide Labs Melatonin Tabs 3mg 90s Lot P1710056

Pharmacy Retailing New Zealand Limited t/a Healthcare Logistics is recalling this Lot of Melatonin in New Zealand. Worldwide Labs Melatonin has been dispensed and supplied to you as an unapproved medicine.

Healthcare Logistics is conducting this recall because a foreign material was found in one tablet from this lot number. This may cause irritation and discomfort if consumed. The contamination was determined to be a short metal strand traced from a wire brush used to clean equipment during manufacturing. Healthcare Logistics is therefore recalling this lot from wholesalers, pharmacies, hospital pharmacies and consumers in New Zealand as a precaution.

Actions for consumers

1. Your pharmacist should contact you if it is determined that you may have been dispensed this lot. The lot number is located at the bottom on the "Supplemental Facts" side panel label of the bottle as shown. If you are unable to identify the lot number because the tablets are not in the original bottle please follow the advice of the pharmacist and return the product you have on hand for a replacement.



**Lot number
P1710056**

2. Please return the affected stock to your pharmacist for replacement.
3. There is a chance that foreign objects in consumed goods can cause discomfort and irritation if ingested. There have been no reports of any adverse events related to this issue. However if you have any concerns seek medical advice from your healthcare professional.

This action has been carried out following consultation with Medsafe, Ministry of Health.

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.

Should you have any questions about this recall, please do not hesitate to contact us on the following details:

Phone: 0508 229 477

Fax: 0508 982 520

Email: recall@healthcarelogistics.co.nz

Yours sincerely,

Matt Taylor
Quality Systems Manager,
Healthcare Logistics