10 July 2024

Wholesaler
Address

URGENT MEDICINE RECALL

TGA Recall Reference Number: RC-2024-RN-00569-1

COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle

ARTG	Item	Batch	Expiry
97690	92298ED	391197	19 October 2024

Dear Wholesaler,

AbbVie Pty Ltd following agreement with the Therapeutic Goods Administration (TGA), is conducting a recall of the above COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle. This recall does not affect any other batches of COMBIGAN or any other AbbVie products.

The potentially affected product has been supplied to your organisation.

This batch has been distributed to wholesalers since June 2023.

What is the problem?

The reason for the recall is a defect identified on the neck of the bottles that could compromise sterility assurance of this batch.

Risk to health:
A Health Hazard Assessment has concluded that there is the reasonable possibility of causing temporary, or medically reversible adverse health consequences with the use or exposure to the affected product, or a remote possibility of serious adverse health consequences with use or exposure to the affected product.

This recall does not affect any other batches of COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle or any other AbbVie Pty Ltd products.

What should you do?

1. Inspect your stock and quarantine affected stock batch 391197 on hand to prevent further use.
2. Complete the attached customer response form immediately, even if you do not have any affected stock.
3. If you have sold any of this batch to another wholesaler, please advise them of the recall and send us their contact details within **1 business day** of receiving this notification.
4. AbbVie will contact retail and hospital pharmacies separately to advise them of the recall and complete Customer Response Form information as required.
5. Submit claim to AbbVie Customer Service for return of affected stock to customerseviceanz@abbvie.com.
6. Ensure your relevant staff members are informed of this recall including warehouse staff.

Place this letter in a prominent position for at least one month.

AbbVie Pty Ltd
Level 7
241 O'Riordan Street
Mascot NSW 2020
Australia

+61 2 9035 8600 (OFFICE)
1800 564 716 (FAX)
abbvie.com.au
ABN: 48 156 384 262

Replacement stock

Replacement stock of COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle is currently available for order.

Contact the following to arrange a replacement:

AbbVie Customer Service
customerserviceanz@abbvie.com Or call 1800 252 224

To report adverse events or for medical information, please contact the below as required:

Adverse Events	**Medical Information**
To report an Adverse Event: Email anzpv@abbvie.com Or call 1800 043 460	Email medinfoanz@abbvie.com Or call 1800 043 460

This recall does not affect any other lot numbers.

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

AbbVie Pty Ltd sincerely regrets any inconvenience caused to your organisation.

Yours Faithfully

John Petteno

Electronically signed by: John Petteno
Reason: Management Approval
Date: Jul 10, 2024 13:22 GMT+10

John Petteno
Associate Director, Third Party and Commercial Quality

AbbVie Pty Ltd
Level 7
241 O'Riordan Street
Mascot NSW 2020
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Customer Response Form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICINE RECALL

TGA Recall Reference Number: RC-2024-RN-00569-1
COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle, ARTG 97690, Batch 391197 exp 19 October 2024.

On behalf of this organisation, I acknowledge receipt of the Recall notice dated 10 July 2024 relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch**	**Quantity of stock received**	**Quantity of unused stock subject to recall (currently in quarantine)**
COMBIGAN® brimonidine tartrate 2.0mg/mL and timolol 5.0mg/mL eye drops bottle	391197		
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other wholesaler?

☐ No

☐ Yes I/we will forward all the recall information to the wholesaler.

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Organisation	AbbVie Pty Ltd
Address	Gateway 241, Level 7 241 O ’Riordan St Mascot 2020
Email	customerserviceanz@abbvie.com
Subject of email	URGENT MEDICINE RECALL of COMBIGAN ARTG 97690 Batch 391197
Telephone no.	1800 252 224