







URGENT
VOLUNTARY PRODUCT RECALL NOTICE
AURO-LOSARTAN 25mg, 50mg and 100mg Tablets
ATTENTION DISTRIBUTORS/WHOLESALERS

Auro Pharma Inc is voluntarily recalling 7 LOTs of AURO-LOSARTAN (25mg, 50mg and 100mg) Tablets due to the presence of impurity (5-(4' - ((5 - (Azidomethyl) - 2-butyl-4-chloro-1H-imidazol-1-yl) methyl)-[1,1' - biphenyl] - 2-yl) - 1H-tetrazole above the acceptable concentration limit in affected lots. Auro Pharma has notified Health Canada about this recall.

STARTING DATE: October 01, 2021
HAZARD CLASSIFICATION: Type I
DEPTH OF RECALL: Retailer/Distributor/Wholesaler (NOT affected at patient level)
ISSUE: Product Safety
RECALLED PRODUCT:

PRODUCT DIN	AURO-LOSARTAN 25mg 02403323	AURO-LOSARTAN 50mg 02403331	AURO-LOSARTAN 100mg 02403358
DESCRIPTION	White to off-white, Oval shaped, biconvex film-coated tablets debossed with 'E' on one side and '45' on other side.	White to off-white, Oval shaped, biconvex film-coated tablets debossed with 'E' on one side and '4' and '5' separated by scoreline on other side.	White to off-white, Oval shaped, biconvex film-coated tablets debossed with 'E' on one side and '47' on other side.
PILL IMAGE			
BOTTLE IMAGE			

Recalled Lot Details:

Sr#	UPC code	Product Description	Lot Number	Expiry Date	First Date of Sale
1.	886965000732	AURO-LOSARTAN 25mg tablets, 100's Bottle	AEJ2520001A	2023-DE-19	Feb 04, 2021
2.	886965000756	AURO-LOSARTAN 50mg tablets, 100's Bottle	AEJ5020001A	2023-DE-16	Apr 01, 2021
3.			AEJ5020002A	2023-DE-17	Jan 22, 2021
4.			AEJ5020003A	2023-DE-18	May 22, 2021
5.	886965000770	AURO-LOSARTAN 100mg tablets, 100's Bottle	AEJ1020001A	2023-DE-19	Feb 04, 2021
6.			AEJ1020002A	2023-DE-20	Jun 02, 2021
7.			AEJ1020003A	2023-DE-21	Mar 02, 2021

Market Authorization: AURO PHARMA INC
3700 Steeles Avenue West, Suite# 402,
Woodbridge, ON, L4L 8K8, Canada

INSTRUCTIONS TO DISTRIBUTORS/WHOLESALERS:

- Suspend all further distribution and sale of the affected product and lots
- Complete and email your **wholesaler** recall response form to mtirecall@inmar.com with your current DC/Wholesaler inventory on hand before October 5, 2021.
- Notify your customers/retailers within **24 hours of receipt** of this recall using the "Recall Notice - Retailer" letter and request that they suspend dispensing the affected lots immediately and return their affected products and lots to you no later than Oct 20, 2021
 - As per GUI-0039, Drug and natural health products recall guide, you are responsible to ensure all affected customers are successfully notified, follow up with non-responders, conduct effectiveness check, and send the information to Auro Pharma to qa@auropharma.ca on a weekly basis.

RETURN PROCEDURE:

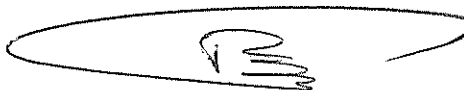
The present recall affects only specified lots of the products.

- Download an Inmar Intelligence Return form from www.returns.org (registration is required for first time users) under "Forms Download" and add any reference or debit note # under Claims.
- Affix Inmar Intelligence's box label and Purolator waybill (1-888-SHIP-123, account #7857889) to the exterior of the shipment and return to
 - Inmar Intelligence
 - 50 Dynamic Drive, Unit 2
 - Toronto (Scarborough), ON
 - M1V 2W2
- Ship all returns received from your direct customers/retailers in the same manner.

CREDIT POLICY:

Recalled products will receive 100% credit based on the exact count fullness returned as per Auro Pharma list price.

Signature:









Rana Harb (PhD) , Vice President –QA, RA & PV
Auro Pharma Inc.

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Market Authorization:		AURO PHARMA INC 3700 Steeles Avenue West, Suite# 402, Woodbridge, ON, L4L 8K8, Canada			

INSTRUCTIONS TO RETAILER:

- Suspend all further dispensing and sale of the affected product and lots
- Follow your point of purchase's recall procedure and return affected product no later than Oct 20, 2021.

Signature:



Rana Harb (PhD) , Vice President –QA, RA & PV

URGENT : PRODUCT RECALL TYPE I

WHOLESALE RECALL RESPONSE FORM

AURO-LOSARTAN 25mg, 50mg and 100mg Tablets

PLEASE COMPLETE THIS FORM AND SEND BY EMAIL TO MTIRECALL@INMAR.COM BY TUESDAY, OCTOBER 5, 2021 (even if you do not have the affected product).

Wholesaler / Distributor Name : _____

Address : _____

City : _____ Province : _____ Postal Code : _____

Telephone : _____ Contact Name : _____

Date : _____ Account # : _____

I confirm **ZERO** inventory of the recalled products/lots listed below

UPC code	DIN	Product Description	Expiry Date	Lot Number	# of bottles to return (full and/or partial*)
886965000732	02403323	AURO-LOSARTAN 25mg tablets, 100's Bottle	2023-DEC	AEJ2520001A	
886965000756	02403331	AURO-LOSARTAN 50mg tablets, 100's Bottle	2023-DEC	AEJ5020001A	
				AEJ5020002A	
				AEJ5020003A	
886965000770	02403358	AURO-LOSARTAN 100mg tablets, 100's Bottle	2023-DEC	AEJ1020001A	
				AEJ1020002A	
				AEJ1020003A	

* Tablet count is not required. Provide the total number of partial bottles.

Affix Inmar Intelligence's box label to the exterior (www.returns.org) and ship collect via Purolator Acct #7857889 to Inmar Intelligence, 50 Dynamic Drive, Unit 2, Scarborough, ON M1V 2W2