



URGENT: CONSUMER LEVEL DRUG RECALL

ZONISAMIDE CAPSULES (25 mg, 50 mg and 100 mg)

NDC 68462-128-01; 25 mg capsules (100 count) **New Batch Added**
NDC 68462-129-01; 50 mg capsules (100 count) **New Batch Added**
NDC 68462-130-01; 100 mg capsules (100 count) **New Batch Added**
NDC 68462-130-05; 100 mg capsules (500 count) **New Batch Added**

April 25, 2022

Dear Customer,

Glenmark Pharmaceuticals Inc., USA is voluntarily extending the August 2021 recall of Zonisamide Capsules (25 mg, 50 mg and 100 mg) (the "Product") to the **Consumer Level**. Please see complete listing of all Product batches being recalled beginning on page 3 of this letter. Please note that we have added new batches to the recall—and have extended the recall to the **Consumer Level**—since our last communication.

The initial recall is due to gaps in the quality system in the Quality Control microbiology laboratory and is being extended as a precaution to promote patient safety. Four batches have been added to the recall due to the lack of stability data.

See details of Product and quantity shipped to your firm and enclosed Product labels for ease in identifying the Product.

To implement this recall, please take the following actions:

- Immediately examine your inventory and quarantine the quantities subject to this recall.
- Identify your customers, and notify them at once of this product recall. If they have recalled product please have them contact Qualanex, LLC at 888-504-2012 so a Recall return packet can be sent to them.
- Please complete, sign, date and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either email to recall@qualanex.com or fax to 847-737-3719.
- Once received, a Return Authorization will be created and emailed to you that should be included with your recalled product.

Glenmark Pharmaceuticals Inc., USA • 750 Corporate Drive, Mahwah, NJ 07430
T: 201.684.8000 • F: 201.831.0080 • www.glenmarkpharma.com/usa



If you have recalled product to return, please use the enclosed postage paid product return label and return to Qualanex, LLC.

If you have any questions regarding your recall return, please contact Qualanex at 888-504-2012. Hours of operation are between 9:00AM – 6:00PM EST.

This voluntary recall is being made with the knowledge of the Food and Drug Administration.

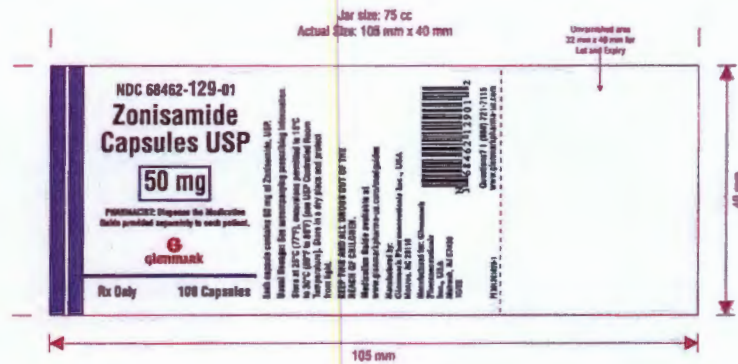
Sincerely,
GLENMARK PHARMACEUTICALS INC., USA

Wilfredo Ortiz
Vice President and Site Head
Glenmark Pharmaceuticals Inc., USA
4147 Goldmine Road
Monroe, NC 28110
Tel: 201-675-9443
E-mail: wilfredo.ortiz@glenmarkpharma.com



ZONISAMIDE CAPSULES USP NDC #68462-128-01 (25 mg capsules, 100 count bottles) NDC #68462-129-01 (50 mg capsules, 100 count bottles) NDC #68462-130-01 (100 mg capsules, 100 count bottles) NDC #68462-130-05 (100 mg capsules, 500 count bottles)			
Batch	NDC	Pack size	Exp. Date
29200052	68462-128-01	25 mg, 100's	4-30-2023
29190043	68462-129-01	50 mg, 100's	5-31-2022
29190044	68462-129-01	50 mg, 100's	5-31-2022
29190045	68462-129-01	50 mg, 100's	5-31-2022
29200064	68462-129-01	50 mg, 100's	5-31-2023
29200014	68462-130-01	100 mg, 100's	2-28-2023
29200015	68462-130-01	100 mg, 100's	3-31-2023
29200016	68462-130-01	100 mg, 100's	3-31-2023
29200030	68462-130-01	100 mg, 100's	5-31-2023
29200031	68462-130-01	100 mg, 100's	5-31-2023
29200032	68462-130-01	100 mg, 100's	5-31-2023
29200033	68462-130-01	100 mg, 100's	6-30-2023
29200037	68462-130-01	100 mg, 100's	6-30-2023
29200038	68462-130-01	100 mg, 100's	6-30-2023
29200039	68462-130-01	100 mg, 100's	7-31-2023
29200041	68462-130-01	100 mg, 100's	7-31-2023
29200042	68462-130-01	100 mg, 100's	7-31-2023
29200048	68462-130-01	100 mg, 100's	8-31-2023
29200049	68462-130-01	100 mg, 100's	8-31-2023
29200050	68462-130-01	100 mg, 100's	8-31-2023
29200053	68462-130-01	100 mg, 100's	4-30-2023
29200072	68462-130-01	100 mg, 100's	11-30-2023
29200073	68462-130-01	100 mg, 100's	11-30-2023
29200074	68462-130-01	100 mg, 100's	11-30-2023
29200075	68462-130-01	100 mg, 100's	11-30-2023
29200076	68462-130-01	100 mg, 100's	11-30-2023
29200014	68462-130-05	100 mg, 500's	2-28-2023
29200015	68462-130-05	100 mg, 500's	3-31-2023
29200016	68462-130-05	100 mg, 500's	3-31-2023
29200054	68462-130-05	100 mg, 500's	4-30-2023

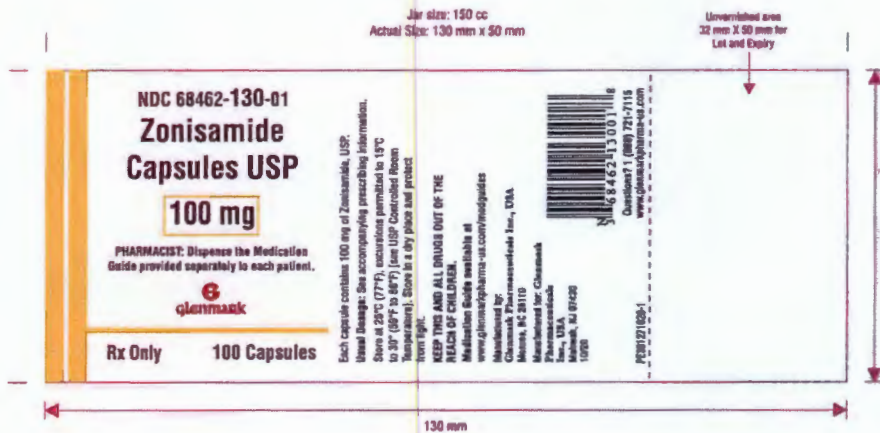
G GLENMARK PHARMACEUTICALS LTD.		DATE:		PANTONE SHADE NO:		186 C		NON PRINTING COLOUR	
PRODUCT NAME: ZONISAMIDE CAPSULES 25 MG		PKG. DEV.:		Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout					
ITEM CODE: PE38125 VERSION: 1020-1		RA		Regulatory Text					
PHARMACODE: NA		PRODUCTION:		Machine Suitability					
COUNTRY: USA		QA:		End Use Test					
LOCATION: MONROE-USA		REMARKS:							
PACK : 100 CAPSULES									
ACTUAL SIZE: 105 mm x 40 mm									
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED									
FCPCD001/01.00									



MINIMUM FONT SIZE: 3.6 pt

DATE: 05-10-2020
VERSION: 04

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO: 185 C 2945 C	
		BLACK HIGH PRINTING COLOUR	
PRODUCT NAME: ZONISAMIDE CAPSULES 50 MG	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE38126 VERSION: 1020-1	RA	Regulatory Text	
PHARMACODE: NA	PRODUCTION:	Machine Suitability	
COUNTRY: USA	QA:	Entire Text	
LOCATION: MONROE-USA	REMARKS:		
PACK: 100 CAPSULES			
ACTUAL SIZE: 105 mm x 40 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC) PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED FCPDC001/01.00			



MINIMUM FONT SIZE: 4.5

DATE: 05-10-2020
VERSION: 04

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO: 186 C 143 C BLACK NON PRINTING COLOUR	
	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
PRODUCT NAME: ZONISAMIDE CAPSULES 100 MG	RA	Regulatory Text	
ITEM CODE: PE38127 VERSION: 1020-1	PRODUCTION:	Machine Suitability	
PHARMACODE: NA	QA:	Entire Text	
COUNTRY: USA	REMARKS:		
LOCATION: MONROE-USA			
PACK : 100 CAPSULES			
ACTUAL SIZE: 130 mm x 50 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED FCPDC001/01.00			



Please fill out the below form and either email your completed response form to recall@qualanex.com or fax to 847-737-3719.

Customer Name: _____ DEA: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone # _____ Fax # _____

Email: _____ Date: _____

Contact Name: _____ Signature: _____

Wholesaler/Distributor Name: _____

Wholesaler Acct. No.: _____

(Recall # 310)

NDC	Lot/Batch	Sealed Bottle(s)	Open Bottle(s)	Open Bottle Capsule Count

We have examined our inventories and have none of the above recalled product in stock:

(Initials) _____

We have identified and notified my customers that were shipped this product.

(Yes-No) _____

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions received on _____ [date].

☐ I do not have any remaining drug product subject to this recall.

Jar size: 750 cc
label size: 180 mm x 85 mm

NDC 68462-130-05

Zonisamide Capsules USP

100 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Rx Only
500 Capsules

Each capsule contains 100 mg of Zonisamide, USP.

Usual Dosage: See accompanying prescribing information.

Store at 25°C (77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Store in a dry place and protect from light.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Medication Guide available at www.glenmarkpharma-us.com/medguides

Manufactured by:
Glenmark Pharmaceuticals Inc., USA
Monroe, NC 28110

Manufactured for: Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
10/20



N 684621300516
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

Unvarnished area
32 mm x 85 mm for
Lot and Expiry

180 mm
85 mm

MINIMUM FONT SIZE: 8.1

DATE: 05-10-2020
VERSION: 04

GLENMARK PHARMACEUTICALS LTD.		DATE:	PANTONE SHADE NO: 186 C 143 C BLACK NON PRINTING COLOUR	
PRODUCT NAME: ZONISAMIDE CAPSULES 100 MG		PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE38128 VERSION: 1020-1		RA	Regulatory Text	
PHARMACODE: NA		PRODUCTION:	Machine Suitability	
COUNTRY: USA		QA:	Entire Text	
LOCATION: MONROE-USA		REMARKS:		
PACK: 500 CAPSULES				
ACTUAL SIZE: 180 mm x 85 mm				
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED				
		FCPDC001/01.00		



CUSTOMER RECALL RETURN RESPONSE FORM

(Recall # 310)

ZONISAMIDE CAPSULES USP			
NDC #68462-128-01 (25 mg capsules, 100 count bottles)			
NDC #68462-129-01 (50 mg capsules, 100 count bottles)			
NDC #68462-130-01 (100 mg capsules, 100 count bottles)			
NDC #68462-130-05 (100 mg capsules, 500 count bottles)			
Batch	NDC	Pack size	Exp. Date
29200052	68462-128-01	25 mg, 100's	4-30-2023
29190043	68462-129-01	50 mg, 100's	5-31-2022
29190044	68462-129-01	50 mg, 100's	5-31-2022
29190045	68462-129-01	50 mg, 100's	5-31-2022
29200064	68462-129-01	50 mg, 100's	5-31-2023
29200014	68462-130-01	100 mg, 100's	2-28-2023
29200015	68462-130-01	100 mg, 100's	3-31-2023
29200016	68462-130-01	100 mg, 100's	3-31-2023
29200030	68462-130-01	100 mg, 100's	5-31-2023
29200031	68462-130-01	100 mg, 100's	5-31-2023
29200032	68462-130-01	100 mg, 100's	5-31-2023
29200033	68462-130-01	100 mg, 100's	6-30-2023
29200037	68462-130-01	100 mg, 100's	6-30-2023
29200038	68462-130-01	100 mg, 100's	6-30-2023
29200039	68462-130-01	100 mg, 100's	7-31-2023
29200041	68462-130-01	100 mg, 100's	7-31-2023
29200042	68462-130-01	100 mg, 100's	7-31-2023
29200048	68462-130-01	100 mg, 100's	8-31-2023
29200049	68462-130-01	100 mg, 100's	8-31-2023
29200050	68462-130-01	100 mg, 100's	8-31-2023
29200053	68462-130-01	100 mg, 100's	4-30-2023
29200072	68462-130-01	100 mg, 100's	11-30-2023
29200073	68462-130-01	100 mg, 100's	11-30-2023
29200074	68462-130-01	100 mg, 100's	11-30-2023
29200075	68462-130-01	100 mg, 100's	11-30-2023
29200076	68462-130-01	100 mg, 100's	11-30-2023
29200014	68462-130-05	100 mg, 500's	2-28-2023
29200015	68462-130-05	100 mg, 500's	3-31-2023
29200016	68462-130-05	100 mg, 500's	3-31-2023
29200054	68462-130-05	100 mg, 500's	4-30-2023