



ANI Pharmaceuticals

URGENT: DRUG PRODUCT RECALL

DATE March 4, 2024

Dear Customer:

This is to inform you of a voluntary product recall involving:

**Digoxin Tablets, USP 125 mcg; Expiry Date: JAN 2025
(Labeled as Novitium Pharma LLC)**

NDC: 70954-201-20, 1000 TABLETS in 1 BOTTLE,

Lot Number: M23172A

See the enclosed product labeling for the drug products for ease in identifying the product at the wholesale level.

This recall has been initiated due to out of specification organic impurity results for the drug product during stability testing. The out of specification results were determined to be the result of cross contamination with another drug product (mycophenolate mofetil). The product was distributed from 03/31/2023 to 06/20/2023.

Immediately examine your inventory and quarantine the subject batch. In addition, if you further distributed this product, please identify your customers, and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

In our best efforts to coordinate the prompt and secure return of the affected product, ANI-New Jersey (formally Novitium Pharma LLC) has contracted with Sedgwick Inc. to provide support for this recall. Instruction for the return of goods to Sedgwick is provided on the Recall Response Form (enclosed). Please complete and return the enclosed response form as soon as possible. If you have any questions, call Sedgwick at 844-388-5532 during normal business hours (8am – 5pm EST).



ANI Pharmaceuticals

Sedgwick Return Management Services

2670 Executive Dr., Ste A

Indianapolis, IN 46241

RE: Event #: 6084

Phone number: 844-388-5532

Fax number: 844-441-2733

Email Id: ani6084@sedgwick.com

ANI-New Jersey kindly requests that you provide Sedgwick Inc. with the quantities of your inventory on hand, the address and contact person at each location, as soon as possible. Enclosed you will find a form on which to record your current inventory of recalled material and the number of customers directly contacted. Please complete and return the form via fax or email (even if you have no inventory to return).

This recall is being carried out to the wholesale level. Your prompt assistance is greatly appreciated.

If you have any questions, please reach out to Sedgwick Inc. at 844-388-5532. For any medical inquiries or to report an adverse event, please contact 1-855-204-1431 Monday-Saturday (24 hours)

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

Enclosure(s)

- **Recall Response Form**
- **Drug Product Labeling**

Thanks,

A handwritten signature in blue ink, appearing to be 'AS' or similar initials.

George Schwab
Vice President- Quality
ANI Pharmaceuticals (N.J.)
70 Lake Drive
East Windsor, NJ 08520



RECALL RETURN RESPONSE FORM

**Digoxin Tablets, USP 125 mcg (Labeled as Novitium Pharma LLC)
M23172A; Exp Date: JAN 2025**

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the recall letter.
- I have checked my stock and have quarantined inventory consisting of _____ units.

Indicate disposition of recalled product:

To Be Returned:

Quantity (# of bottles):
Returned Date:
Return Method:

Destroyed

Quantity (# of bottles):
Method of Destruction:

- I have identified and notified my customers that were shipped or may have been shipped this product.
- We have NONE of the recalled lots in stock.

Any adverse events associated with recalled product? Yes No

If yes, please explain:

Please check the appropriate box(es) to describe your business.

- wholesaler/distributor
- retailer
- pharmacy – retail
- hospital/medical facility
- hospital pharmacies
- medical laboratory
- Other: _____



ANI Pharmaceuticals

Retail Customer: _____

Contact Name: _____

Contact Phone Number: _____ Contact Fax Number: _____

Address: _____ City, State, & Zip: _____

Wholesaler Name: _____ Wholesaler City & State: _____

PLEASE E-MAIL OR MAIL COMPLETED RESPONSE FORM TO Email:
ani6084@sedgwick.com

OR MAIL TO:

Sedgwick Return Management Services
2670 Executive Dr., Ste A
Indianapolis, IN 46241
RE: Event #: 6084

Phone Number: 844-388-5532

Fax Number: 844-441-2733

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 1. Recommended Maximum Daily Intake... Table 2. Recommended Maximum Daily Intake... Table 3. Recommended Maximum Daily Intake... Table 4. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 5. Recommended Maximum Daily Intake... Table 6. Recommended Maximum Daily Intake... Table 7. Recommended Maximum Daily Intake... Table 8. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 9. Recommended Maximum Daily Intake... Table 10. Recommended Maximum Daily Intake... Table 11. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 12. Recommended Maximum Daily Intake... Table 13. Recommended Maximum Daily Intake... Table 14. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 15. Recommended Maximum Daily Intake... Table 16. Recommended Maximum Daily Intake... Table 17. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 18. Recommended Maximum Daily Intake... Table 19. Recommended Maximum Daily Intake... Table 20. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 21. Recommended Maximum Daily Intake... Table 22. Recommended Maximum Daily Intake... Table 23. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 24. Recommended Maximum Daily Intake... Table 25. Recommended Maximum Daily Intake... Table 26. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 27. Recommended Maximum Daily Intake... Table 28. Recommended Maximum Daily Intake... Table 29. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...


Table 30. Recommended Maximum Daily Intake... Table 31. Recommended Maximum Daily Intake... Table 32. Recommended Maximum Daily Intake...

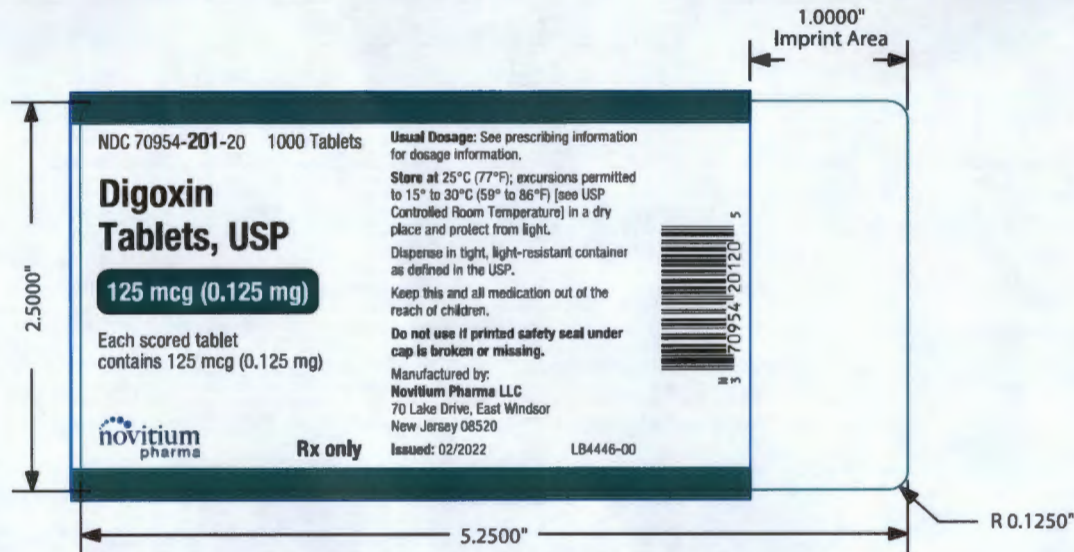
...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...


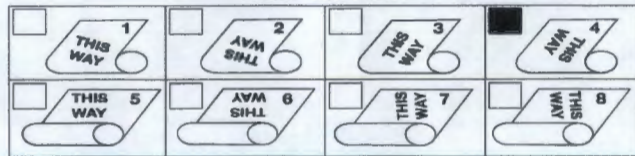
Table 33. Recommended Maximum Daily Intake... Table 34. Recommended Maximum Daily Intake... Table 35. Recommended Maximum Daily Intake...

...the high blood pressure... 10 mg... 20 mg... 30 mg... 40 mg... 50 mg... 60 mg... 70 mg... 80 mg... 90 mg... 100 mg...

Table 36. Recommended Maximum Daily Intake... Table 37. Recommended Maximum Daily Intake... Table 38. Recommended Maximum Daily Intake...

	92 North Main Street, Windsor, NJ-08561 Phone #609-448-9400 Fax #609-448-9600	Proof #	2	Proof Date	02/10/2022 3:59 PM
		Artwork Prepared by	SS	Job Number	MGL10485
		Manufactured FOR		Manufactured BY	Novitium Pharma



Customer Description	1000' Count Digoxin Tablets, USP 125 mcg (Novitium Pharma)						
Customer Name	Novitium Pharma	NDC #	70954-201-10	REVISION #	02/2022	# of COLOR	5
Label Size	2.5" x 5.25"	UPC CODE #	370954201105	CUSTOMER ITEM #	LB4446-00	BARCODE TYPE	UPC-A
COLORS CMYK SPOT  Note: Proof colors do not represent exact PMS colors. Please refer to the current PMS guide.				REWIND DIRECTION 			
SPECIAL INSTRUCTIONS & NOTES				The above proof is verified and the same is : <input type="checkbox"/> Approved OK to Print. <input type="checkbox"/> Approved OK for FDA submission only. <input type="checkbox"/> Changes required submit revised proof.			
CUSTOMER							
Verified By (Name & Sign)				Approved By (Name & Sign)			
FOR MEDLIT GRAPHICS ONLY							
HISTORY:	Noted Changes						

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