

FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user-facilities, importers, distributors
and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291

Expires: 6-30-2025

See PRA statement on page 6.

FDA USE ONLY

Mfr report #

UF/Importer Report #

Exemption/Variance #

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900.

A. PATIENT INFORMATION**1. Patient Identifier** (*In confidence*)

[REDACTED]

2. Age☒ Year(s) ☐ Week(s)☐ Month(s) ☐ Day(s)or Date of Birth (*e.g., 01-Jan-1900*)

27-Jan-

[REDACTED]

3. Sex: Enter the patient's sex at birth
(*the sex that a person has or was
assigned to at birth*).☒ Male☐ Female**SECTION REMOVED****4. Weight**160.0(☐ lb☐ kg**5. Ethnicity** (*Check one*)☐ Hispanic/Latino☒ Not Hispanic/Latino**6. Race** (*check all that apply*)☐ American Indian/Alaska Native☒ Asian☐ Black or African American☐ Native Hawaiian/
Other Pacific Islander☐ White**B. ADVERSE EVENT OR PRODUCT PROBLEM****1. Type of Report** (*check all that apply*)☒ Adverse Event☐ Product Problem(*e.g., defects/malfunctions*)**2. Outcome Attributed to Adverse Event** (*check all that apply*)☐ Death – Date of death (*01-JAN-1900*):☒ Life-threatening☒ Hospitalization (initial or prolonged)☐ Other Serious or Important
Medical Events☐ Required Intervention to Prevent
Permanent Impairment/Damage☐ Disability or Permanent Damage☐ Congenital Anomaly/Birth Defects**3. Date of Event** (*01-JAN-1900*)

17-Jan-2025

4. Date of this Report (*01-JAN-1900*)

22-Jan-2025

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

* Please see instructions

5. Describe Event or Problem

On January 19, 2025, the patient experienced acute shortness of breath, dizziness, and chest tightness approximately 30 minutes after taking X for the eighth consecutive day. Symptoms escalated over the next hour, leading to an emergency room visit and subsequent hospital admission. Clinical evaluation confirmed a hypertensive crisis potentially triggered by the medication. No prior history of similar symptoms was reported. After discontinuation of X, the patient's condition stabilized within 48 hours.

6. Relevant Test/Laboratory Data	Date (01-JAN-1900)	Relevant Test/Laboratory Data	Date (01-JAN-1900)
<div>█essure</div> <div>Chest X-ray</div> <div>Basic Metabolic Panel & CBC</div>			

Additional comments

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, tobacco product use, alcohol use, and liver/kidney problems, etc.)

Drug Y with tobacco

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. Name, Strength, Manufacturer/Compounder

Product Name	Strength	Unit
Drug X	10	GRAM(S) - GM
NDC # or Unique ID	Manufacturer/Compounder Name	Lot #
	Apex Compounding	

2. List Medical Product and Treatment Given at the Same Time of the Event and Date (Do not include treatment for initial event)

Dates of Use: 01/12/2025 – 01/20/2025Diagnosis for Use: HypertensionEvent Onset Date: 01/19/2025

3. Dose or Amount	Frequency	Route
Unit	--	--
--	Other Frequency	Other Route

4. Treatment Dates/Therapy Dates (give best estimate of length of treatment (start/stop) or date of dose reduction.)

Therapy started on (e.g., 01-Jan-1900)	Therapy stopped on (e.g., 01-Jan-1900)	Dose Reduced (e.g., 01-Jan-1900)	OR	Duration	Unit
					--

5. Diagnosis for use (indication)

6. Product Type (check all that apply)

7. Expiration Date (e.g., 01-Jan-1900)

☐ OTC ☐ Generic
☐ Compounded ☐ Biosimilar

8. Event Abated after use Stopped or Dose Reduced?

☐ Yes ☐ No ☐ Doesn't apply

9. Event Reappeared after Reintroduction?

☐ Yes ☐ No ☐ Doesn't apply

SUSPECT PRODUCT #2**1. Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--
NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. List Medical Product and Treatment Given at the Same Time of the Event and Date *(Do not include treatment for initial event)*

3. Dose or Amount	Frequency	Route
Unit	--	--
--	Other Frequency	Other Route

4. Treatment Dates/Therapy Dates *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on <i>(e.g., 01-Jan-1900)</i>	Therapy stopped on <i>(e.g., 01-Jan-1900)</i>	Dose Reduced <i>(e.g., 01-Jan-1900)</i>	OR	Duration	Unit
					--

5. Diagnosis for use <i>(indication)</i>	6. Product Type <i>(check all that apply)</i>	7. Expiration Date <i>(e.g., 01-Jan-1900)</i>
	<input type="checkbox"/> OTC <input type="checkbox"/> Generic <input type="checkbox"/> Compounded <input type="checkbox"/> Biosimilar	

8. Event Abated after use Stopped or Dose Reduced? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply	9. Event Reappeared after Reintroduction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
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D. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Common Device Name	2b. Procode
3. Manufacturer Name, City and State		
4. Model #	Lot #	Catalog #
Expiration Date <i>(01-JAN-1900)</i>	Serial #	

Unique Device Identifier (UDI) #

5. Operator of Device

☐ Health Professional ☐ Patient/Consumer
☐ Other

6a. If Implanted, Give Date (01-JAN-1900)

6b. If Explanted, Give Date (01-JAN-1900)

7a. Is this a single-use device that was reprocessed and reused on a patient?

☐ Yes ☐ No

7b. If yes, enter the name and address of the reprocessor

8. Was this device ever serviced by a third-party servicer?

☐ Yes ☐ No ☐ Unknown

9. Is this Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No
☐ Returned to manufacturer on (01-JAN-1900)

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Product Name

Therapy Start Date (01-JAN-1900)

Therapy End Date (01-JAN-1900)

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

E. INITIAL REPORTER

1. Name and Address

Last Name

First Name

Address

City

State/Province/Region

ZIP/Postal Code

Country

Phone #

Email

2. Health Professional?

☐ Yes ☐ No

3. Occupation (Select from list)

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4. Initial reporter also sent report to FDA

☐ Yes ☐ No ☐ Unknown

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. User Facility/Importer Report Number		
3. User Facility or Importer Name/Address		4. Contact Person		5. Phone Number
		6. Date User Facility or Importer Became Aware of Event (01-JAN-1900)		7. Type of Report
8. Date of This Report (01-JAN-1900)		9. Approximate Age of Device		
10. Adverse Event Problem (Refer to coding manual)				
Health Effect – Clinical Code		Health Effect – Impact Code		Medical Device Problem Code
				Component Code
11. Report Sent to FDA? (If Yes, enter date (01-JAN-1900)) <input type="checkbox"/> Yes <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other (Specify) <input type="checkbox"/> Home <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Hospital <input type="checkbox"/> Nursing Home		
13. Report Sent to Manufacturer? (If Yes, enter date (01-JAN-1900)) <input type="checkbox"/> Yes <input type="checkbox"/> No		14. Manufacturer Name/Address		

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility				
Name		Email Address		Phone Number
Address				
Compounding Outsourcing Facility 503B? <input type="checkbox"/> Check box if applicable		Outsourcing Facility		
2. Report Source (check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Literature <input type="checkbox"/> Health Professional <input type="checkbox"/> Company Representative <input type="checkbox"/> Study <input type="checkbox"/> Consumer <input type="checkbox"/> Use Facility <input type="checkbox"/> Distributor/Importer <input type="checkbox"/> Other (Please list)				3. Date Received by Manufacturer (01-JAN-1900)
4. NDA #	ANDA #	IND #	BLA #	PMA/510(k) #
Check all that apply: <input type="checkbox"/> Combination product <input type="checkbox"/> Pre-ANDA <input type="checkbox"/> Pre-1938 <input type="checkbox"/> OTC <input type="checkbox"/> Compounded Product				
5. If IND/Pre-ANDA, Give Protocol #		6. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> Periodic <input type="checkbox"/> Follow-up # <input type="checkbox"/> 7-day <input type="checkbox"/> 30-day <input type="checkbox"/> Initial		
7. Adverse Event Term(s)			8. Manufacturer Report Number	

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event *(check all that apply.)*

- ☐ Death ☐ Malfunction
☐ Serious Injury ☐ Summary Report
 No. of events summarized

2. If Follow-up, What Type?

- ☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

- ☐ Yes ☐ No

4. Device Manufacture Date (01-JAN-1900)

5. Labeled for Single Use?

- ☐ Yes ☐ No

6. Adverse Event Problem *(Refer to coding manual)*

Health Effect – Clinical Code

Health Effect – Impact Code

Medical Device Problem Code

Component Code

Type of Investigation

Investigation Findings

Investigation Conclusions

7. If Remedial Action Initiated, Check Type

- ☐ Recall ☐ Relabeling ☐ Patient Monitoring
☐ Repair ☐ Notification ☐ Modification/Adjustment
☐ Replace ☐ Inspection ☐ Other:

8. Usage of Device

- ☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:

10. Related Report Number

11. Additional Manufacturer Narrative

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 73 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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