

URGENT: DRUG PRODUCT RECALL NOTIFICATION

Date: October 6, 2025

Dear Valued Customer:

Avet Pharmaceuticals Inc. ("Avet") located in East Brunswick, New Jersey, is initiating a voluntary recall of 9 lots of Desipramine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg. A full list of impacted lot numbers is provided in the below table. This recall is being conducted in coordination with the FDA to the Retail level. The drug product is manufactured by USV Private Ltd. (Daman, India) and is distributed by Avet. This recall is being initiated due to N-Nitroso Desipramine impurity exceeding the permissible acceptable daily intake level.

Product Name	Dosage / Package	NDC	Lot (s)	Expiry
Desipramine Hydrochloride Tablets USP	10 mg, 100's	23155-578-01	18036908	Sep-26
Desipramine Hydrochloride Tablets USP	25 mg, 100's	23155-579-01	18035876	Dec-25
Desipramine Hydrochloride Tablets USP	25 mg, 100's	23155-579-01	18036909	Sep-26
Desipramine Hydrochloride Tablets USP	50 mg, 100's	23155-580-01	18036713	Aug-26
Desipramine Hydrochloride Tablets USP	75 mg, 100's	23155-581-01	18036662	Jul-26
Desipramine Hydrochloride Tablets USP	75 mg, 100's	23155-581-01	18037649	Mar-27
Desipramine Hydrochloride Tablets USP	100 mg, 100's	23155-582-01	18035574	Oct-25
Desipramine Hydrochloride Tablets USP	100 mg, 100's	23155-582-01	18036758	Aug-26
Desipramine Hydrochloride Tablets USP	150 mg, 50's	23155-583-25	18035739	Nov-25

Please note that there are no adverse events or any complaints that were reported to Avet for the identified lots of Desipramine Hydrochloride Tablets USP.

In light of this information, we request you immediately examine your inventory and quarantine the subject product lots. In addition if you have further distributed this product, please identify your customers and notify them at once about this product recall. Please return the "Recall Response Form" to Avet designated recall service provider, Inmar as indicated below in this letter.

Page 1 of 7





Inmar will provide you with a recall return package that will include a postage paid product return label to return any recalled product to the address provided below.

Please take the following actions:

1. Check your inventory to see if you have any of the recalled product in stock. If so, place the product under quarantine and do not continue to use or distribute.
2. Return product responses to the following address:
Avet Pharmaceuticals Inc.
C/o Inmar Rx Solutions, Attn: Recall Coordinator,
3845 Grand Lakes Way, Suite 100
Grand Prairie, TX 75050
3. Complete the enclosed "Recall Response Form" and return via fax to 817-868-5362 or email to rxrecalls@inmar.com. Consumers with any returns related questions should contact Inmar at 1-855-860-9315 (Monday – Friday, 9:00 am – 5:00 pm EST) and or rxrecalls@inmar.com.

Any adverse reactions or quality problems associated with the use of this product may be reported by calling Avet's pharmacovigilance service provider at **1-866-901-3784** at any time. In addition, any such problems may also be reported to FDA's MedWatch Adverse Event Reporting program either by phone, online, by regular mail or by fax via the information provided below:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

We apologize for any inconvenience caused by this product recall, and we appreciate your cooperation and support.

This recall is made with the full knowledge of the U.S. Food and Drug Administration.

Sincerely,

**Bernadette
Attinger**

Digitally signed by Bernadette
Attinger
Date: 2025.10.06 13:07:58
-04'00'

Bernadette Attinger
VP Regulatory Affairs and Project Management
Avet Pharmaceuticals Inc

See product labeling on the following pages for ease of identifying the product.





Avet Pharmaceuticals Inc.

Affordable. Accessible. Quality Medicines.

Product Container Labels

NDC 23155-578-01
Desipramine Hydrochloride Tablets, USP
10 mg

PHARMACIST: Dispense the enclosed Medication Guide to each patient.

100 Tablets Rx only

Avet Pharma

Each tablet contains:
Desipramine hydrochloride, USP 10 mg

Dosage and Administration:
See package insert for dosage information.
Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).
Protect from excessive heat.

Pharmacist:
Dispense in tight container with child-resistant closure.
WARNING: Keep out of reach of children. Keep tightly closed.

Manufactured by:
USV Private Limited
Daman - 396210, India

Manufactured for:
Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023
Code No.: DD/DRUGS/DD/2913017560

OPZ Area
61 mm x 13.5 mm (L x H)

N 23155578010

NDC 23155-579-01
Desipramine Hydrochloride Tablets, USP
25 mg

PHARMACIST: Dispense the enclosed Medication Guide to each patient.

100 Tablets Rx only

Avet Pharma

Each tablet contains:
Desipramine hydrochloride, USP 25 mg

Dosage and Administration:
See package insert for dosage information.
Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).
Protect from excessive heat.

Pharmacist:
Dispense in tight container with child-resistant closure.
WARNING: Keep out of reach of children. Keep tightly closed.

Manufactured by:
USV Private Limited
Daman - 396210, India

Manufactured for:
Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023
Code No.: DD/DRUGS/DD/2913017570

OPZ Area
61 mm x 13.5 mm (L x H)

N 231555790117

NDC 23155-580-01
Desipramine Hydrochloride Tablets, USP
50 mg

PHARMACIST: Dispense the enclosed Medication Guide to each patient.

100 Tablets Rx only

Avet Pharma

Each tablet contains:
Desipramine hydrochloride, USP 50 mg

Dosage and Administration:
See package insert for dosage information.
Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).
Protect from excessive heat.

Pharmacist:
Dispense in tight container with child-resistant closure.
WARNING: Keep out of reach of children. Keep tightly closed.

Manufactured by:
USV Private Limited
Daman - 396210, India

Manufactured for:
Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023
Code No.: DD/DRUGS/DD/2913017569

OPZ Area
61 mm x 13.5 mm (L x H)

N 231555800113





Avet Pharmaceuticals Inc.

Affordable. Accessible. Quality Medicines.

NDC 23155-581-01

**Desipramine
Hydrochloride
Tablets, USP**

75 mg

PHARMACIST: Dispense the enclosed
Medication Guide to each patient.

100 Tablets

Rx only



Each tablet contains:

Desipramine hydrochloride,
USP 75 mg

Dosage and Administration:
See package insert for dosage
information.

Store at 20° to 25°C (68° to
77°F) (see USP Controlled
Room Temperature).

Protect from excessive heat.

Pharmacist:

Dispense in tight container
with child-resistant closure.

WARNING: Keep out of reach
of children. Keep tightly closed.

Manufactured by:

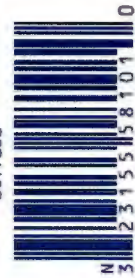
USV Private Limited
Daman - 396210, India

Manufactured for:

Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023

Code No.: DD/DRUGS/DD/291
3017568



OPZ Area

61 mm x 13.5 mm (L x H)

NDC 23155-582-01

**Desipramine
Hydrochloride
Tablets, USP**

100 mg

PHARMACIST: Dispense the enclosed
Medication Guide to each patient.

100 Tablets

Rx only



Each tablet contains:

Desipramine hydrochloride,
USP 100 mg

Dosage and Administration:
See package insert for dosage
information.

Store at 20° to 25°C (68° to
77°F) (see USP Controlled
Room Temperature).

Protect from excessive heat.

Pharmacist:

Dispense in tight container
with child-resistant closure.

WARNING: Keep out of reach
of children. Keep tightly closed.

Manufactured by:

USV Private Limited
Daman - 396210, India

Manufactured for:

Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023

Code No.: DD/DRUGS/DD/291
3017567



OPZ Area

61 mm x 13.5 mm (L x H)

NDC 23155-583-25

**Desipramine
Hydrochloride
Tablets, USP**

150 mg

PHARMACIST: Dispense the enclosed
Medication Guide to each patient.

50 Tablets

Rx only



Each tablet contains:

Desipramine hydrochloride,
USP 150 mg

Dosage and Administration:
See package insert for dosage
information.

Store at 20° to 25°C (68° to
77°F) (see USP Controlled
Room Temperature).

Protect from excessive heat.

Pharmacist:

Dispense in tight container
with child-resistant closure.

WARNING: Keep out of reach
of children. Keep tightly closed.

Manufactured by:

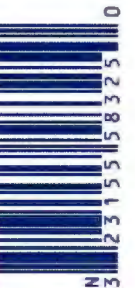
USV Private Limited
Daman - 396210, India

Manufactured for:

Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

Rev. 06/2023

Code No.: DD/DRUGS/DD/291
3017561



OPZ Area

61 mm x 13.5 mm (L x H)





Avet Pharmaceuticals Inc.®

Affordable. Accessible. Quality Medicines.

Shipper Labels:

Manufactured for: Avet Pharmaceuticals Inc. ✓
East Brunswick, NJ 08816, USA ✓
Manufactured by: USV Private Limited ✓
Daman-396210, India ✓

Desipramine Hydrochloride ✓
Tablets, USP 10 mg ✓
Pack Size: 100 Tablets ✓
Store at 20° to 25°C (68° to 77°F) ✓
NDC 23155-578-01 ✓
EXP: 2026/09 ✓ LOT: 18036908 ✓ QTY: 42 ✓

(17) 260930 (10) 18036908 (30) 42 ✓

(01) 30323155578011 (21) RKH2GRR6PTRR
Shipper No.: 000

Manufactured for: Avet Pharmaceuticals Inc. ✓
East Brunswick, NJ 08816, USA ✓
Manufactured by: USV Private Limited ✓
Daman-396210, India ✓

Desipramine Hydrochloride ✓
Tablets, USP 10 mg ✓
Pack Size: 100 Tablets ✓
Store at 20° to 25°C (68° to 77°F) ✓
NDC 23155-578-01 ✓
EXP: 2026/09 ✓ LOT: 18036908 ✓ QTY: 42 ✓

(17) 260930 (10) 18036908 (30) 42 ✓

(01) 30323155578011 (21) RKH2GRR6PTRR
Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc. ✓
East Brunswick, NJ 08816, USA ✓
Manufactured by: USV Private Limited ✓
Daman-396210, India ✓

Desipramine Hydrochloride ✓
Tablets, USP 25 mg ✓
Pack Size: 100 Tablets ✓
Store at 20° to 25°C (68° to 77°F) ✓
NDC 23155-579-01 ✓
EXP: 12/2025 ✓ LOT: 18035876 ✓ QTY: 42 ✓

(17) 251231 (10) 18035876 (30) 42 ✓

(01) 30323155579018 (21) 8ZYVKRW3362E
Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc. ✓
East Brunswick, NJ 08816, USA ✓
Manufactured by: USV Private Limited ✓
Daman-396210, India ✓

Desipramine Hydrochloride ✓
Tablets, USP 25 mg ✓
Pack Size: 100 Tablets ✓
Store at 20° to 25°C (68° to 77°F) ✓
NDC 23155-579-01 ✓
EXP: 12/2025 ✓ LOT: 18035876 ✓ QTY: 42 ✓

(17) 251231 (10) 18035876 (30) 42 ✓

(01) 30323155579018 (21) 8ZYVKRW3362E
Shipper No.: 000





Avet Pharmaceuticals Inc.®

Affordable. Accessible. Quality Medicines.

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India
Desipramine Hydrochloride
Tablets, USP 50 mg
Pack Size: 100 Tablets
Store at 20° to 25°C (68° to 77°F)
NDC 23155-580-01
EXP: 2026/08 LOT: 18036713 QTY: 42
(17) 260831 (10) 18036713 (30) 42
(01) 30323155580014 (21) 457W8RRX64W0
Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India
Desipramine Hydrochloride
Tablets, USP 50 mg
Pack Size: 100 Tablets
Store at 20° to 25°C (68° to 77°F)
NDC 23155-580-01
EXP: 2026/08 LOT: 18036713 QTY: 42
(17) 260831 (10) 18036713 (30) 42
(01) 30323155580014 (21) 457W8RRX64W0
Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India
Desipramine Hydrochloride
Tablets, USP 75 mg
Pack Size: 100 Tablets
Store at 20° to 25°C (68° to 77°F)
NDC 23155-581-01
EXP: 2026/07 LOT: 18036662 QTY: 42
(17) 260731 (10) 18036662 (30) 42
(01) 30323155581011 (21) PMSEXY57W1XC
Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India
Desipramine Hydrochloride
Tablets, USP 75 mg
Pack Size: 100 Tablets
Store at 20° to 25°C (68° to 77°F)
NDC 23155-581-01
EXP: 2026/07 LOT: 18036662 QTY: 42
(17) 260731 (10) 18036662 (30) 42
(01) 30323155581011 (21) PMSEXY57W1XC
Shipper No.: 000





Avet Pharmaceuticals Inc.®

Affordable. Accessible. Quality Medicines.



Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India

**Desipramine Hydrochloride
Tablets, USP 100 mg**

Pack Size: 100 Tablets

Store at 20° to 25°C (68° to 77°F)

NDC 23155-582-01

EXP: 10/2025 LOT: 18035574 QTY: 24



(17) 251031 (10) 18035574 (30) 24



(01) 30323155582018 (21) 7AZYXW6RK8G0

Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India

**Desipramine Hydrochloride
Tablets, USP 150 mg**

Pack Size: 50 Tablets

Store at 20° to 25°C (68° to 77°F)

NDC 23155-583-25

EXP: 11/2025 LOT: 18035739 QTY: 0



(00) 403231550003609641

Shipper No.: 092

PARTIAL

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India

**Desipramine Hydrochloride
Tablets, USP 100 mg**

Pack Size: 100 Tablets

Store at 20° to 25°C (68° to 77°F)

NDC 23155-582-01

EXP: 10/2025 LOT: 18035574 QTY: 24



(17) 251031 (10) 18035574 (30) 24



(01) 30323155582018 (21) 7AZYXW6RK8G0

Shipper No.: 000

Distributed by: Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816, USA
Manufactured by: USV Private Limited
Daman-396210, India

**Desipramine Hydrochloride
Tablets, USP 150 mg**

Pack Size: 50 Tablets

Store at 20° to 25°C (68° to 77°F)

NDC 23155-583-25

EXP: 11/2025 LOT: 18035739 QTY: 0



(00) 403231550003609641

Shipper No.: 092

PARTIAL



RECALL RESPONSE FORM

Product RECALL Desipramine HCl Tablets USP– October 6, 2025

Product Details:

Product Name	Dosage / Package	NDC	Lot (s)	Expiry
Desipramine HCl Tablets USP	10 mg, 100's	23155-578-01	18036908	Sep-26
Desipramine HCl Tablets USP	25 mg, 100's	23155-579-01	18035876	Dec-25
Desipramine HCl Tablets USP	25 mg, 100's	23155-579-01	18036909	Sep-26
Desipramine HCl Tablets USP	50 mg, 100's	23155-580-01	18036713	Aug-26
Desipramine HCl Tablets USP	75 mg, 100's	23155-581-01	18036662	Jul-26
Desipramine HCl Tablets USP	75 mg, 100's	23155-581-01	18037649	Mar-27
Desipramine HCl Tablets USP	100 mg, 100's	23155-582-01	18035574	Oct-25
Desipramine HCl Tablets USP	100 mg, 100's	23155-582-01	18036758	Aug-26
Desipramine HCl Tablets USP	150 mg, 50's	23155-583-25	18035739	Nov-25

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Company Name _____ DEA # _____
DEA # is required, if not provided the processing of your form will be delayed.

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

I have checked my stock and:

☐ Do not have any stock of the recalled **items**.

OR

☐ Have quarantined and listed in the box below the qty of recalled units I will be returning to Inmar, as soon as possible.

Lot #	Exp. Date	Strength	Pkg Size	NDC	Qty of btls returning



If you did not purchase the product directly from the Manufacturer please complete the below section.

Purchased From: Wholesaler Name _____ DEA # _____

City _____ State _____

If you have any questions regarding this form or product return please contact Inmar at 1-855-860-9315
Office hours 9am to 5pm EST, Mon thru Fri. Please return this form via fax to 817-868-5362 or email to
rxrecalls@inmar.com.

