



April 19, 2021

**URGENT DRUG RECALL FOR  
ASENAPINE SUBLINGUAL TABLETS, 5 MG AND 10 MG**

Dear Valued Customer:

This is to inform you of a voluntary product recall involving Sigmapharm's Asenapine Sublingual Tablets, 5 mg and 10 mg for the lot numbers listed below.

| Product                             | NDC Number   | UPC Code       | Lot Numbers | Expiration Date | Distribution Date   | Manufacturer and Distributor |
|-------------------------------------|--------------|----------------|-------------|-----------------|---------------------|------------------------------|
| Asenapine Sublingual Tablets, 5 mg  | 42794-016-10 | 3 4279401610 3 | 2012501     | AUG 2022        | DEC 2020            | Sigmapharm Laboratories, LLC |
|                                     | 42794-016-10 | 3 4279401610 3 | 2012601     | AUG 2022        | DEC 2020 – JAN 2021 |                              |
|                                     | 42794-016-10 | 3 4279401610 3 | 2012701     | AUG 2022        | JAN 2021 – APR 2021 |                              |
|                                     | 42794-016-10 | 3 4279401610 3 | 2100701     | AUG 2022        | APR 2021            |                              |
| Asenapine Sublingual Tablets, 10 mg | 42794-017-10 | 3 4279401710 0 | 2012801     | AUG 2022        | DEC 2020            |                              |
|                                     | 42794-017-10 | 3 4279401710 0 | 2012901     | AUG 2022        | DEC 2020 – JAN 2021 |                              |
|                                     | 42794-017-10 | 3 4279401710 0 | 2013001     | AUG 2022        | JAN 2021 – FEB 2021 |                              |
|                                     | 42794-017-10 | 3 4279401710 0 | 2100101     | NOV 2022        | FEB 2021            |                              |
|                                     | 42794-017-10 | 3 4279401710 0 | 2100501     | AUG 2022        | FEB 2021 – APR 2021 |                              |

See enclosed product label for further ease in identifying the product.

This recall has been initiated due to the use of Art Cherry as a flavoring agent instead of Art Black Cherry Flavor. Use of this product is not likely to cause any adverse health consequences.

We began shipping this product on December 14, 2020.

We ask for your cooperation in taking the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately stop distribution of these lots.
3. A credit memo will be issued covering the quantity of your product returned.

Return product to: Eversana  
c/o SigmaPharm recall  
ATTN: Returns Department  
4580 S. Mendenhall  
Memphis, TN 38141

NOTE: To request a prepaid shipping label please complete and return the enclosed "Customer Recall Return Response Form" to the email or fax below (section 5). The prepaid shipping label will be sent to the email address

Sigmapharm Laboratories, LLC • 3375 Progress Drive • Bensalem, PA 19020 • USA  
Tel: +01 215-352-6655 • Fax: +01 215-352-6644 • www.sigmapharm.com



provided. The email will be coming from EVERSANA within 5 business days. Please check the spam folder if you do not see it in your inbox. **Please note the FedEx link is only valid for 10 days.**

\*Wholesalers please send debit memo via email or fax (section 5).

4. If you have further distributed this product to other wholesalers, please identify and notify them at once of this product recall. Your notification should include a copy of this recall notification letter and customer recall return response form.
5. Even if you do not have the recalled product in your inventory, please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and email the form to us at [DDNRegulatory@Eversana.com](mailto:DDNRegulatory@Eversana.com) and CC: [SigmaPharmCS@Eversana.com](mailto:SigmaPharmCS@Eversana.com). The completed form may also be faxed to 1- 414-434-6690.

This recall should be carried out to the **wholesale level**. Your assistance is appreciated and necessary to prevent further distribution of the product.

If you have any questions related to the return of these products, contact Customer Service at 1-855-206-7815, option 1 on Monday through Friday between 8 am – 7 pm CST. If you have any other questions related to this recall, please contact Sigmapharm's Sales & Marketing Department: Mr. McKee Moore (at 215-352-6655, Ext 258) or Mr. Robert Citrino (at 215-352-6655, Ext 259).

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

Sincerely,

A handwritten signature in black ink that reads "Prakash Patel".

Prakash Patel  
Senior Vice President, Quality Operations Division  
SigmaPharm Laboratories, LLC  
Enclosure(s):  
Product Labels  
Customer Recall Return Response Form

## Individual Package Labeling for Asenapine Sublingual Tablets, 5 mg

NDC 42794-016-10  
**Asenapine Sublingual Tablets**  
**5 mg**  
Do not split, cut or crush tablet. Do not chew or swallow tablet.  
DISPENSE ONLY IN ORIGINAL CONTAINER.

Each sublingual tablet contains: 5 mg asenapine (as maleate) and inactive ingredients.

Usual Dosage: See package insert for dosage information.

Storage: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Sigmapharm Laboratories, LLC  
Bensalem, PA 19020

Read how to use medication.  
**IMPORTANT:**

- For sublingual use only.
- Do not remove tablet until ready to administer.
- Use dry hands when handling tablet.

Place the whole tablet under tongue and allow it to dissolve completely.

Do not eat or drink for 10 minutes.

10 minutes





  
Rx only  
60 Tablets

Black Cherry Flavor

N 3 42794 01610 3 L047.05-R0718

## Individual Package Labeling for Asenapine Sublingual Tablets, 10 mg

NDC 42794-017-10  
**Asenapine Sublingual Tablets**  
**10 mg**  
Do not split, cut or crush tablet. Do not chew or swallow tablet.  
DISPENSE ONLY IN ORIGINAL CONTAINER.

Each sublingual tablet contains: 10 mg asenapine (as maleate) and inactive ingredients.

Usual Dosage: See package insert for dosage information.

Storage: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Sigmapharm Laboratories, LLC  
Bensalem, PA 19020

Read how to use medication.  
**IMPORTANT:**

- For sublingual use only.
- Do not remove tablet until ready to administer.
- Use dry hands when handling tablet.

Place the whole tablet under tongue and allow it to dissolve completely.

Do not eat or drink for 10 minutes.

10 minutes





  
Rx only  
60 Tablets

Black Cherry Flavor

N 3 42794 01710 0 L049.05-R0718



April 19, 2021

**RECALL RESPONSE RETURN FORM**

**RECALL OF ASENAPINE SUBLINGUAL TABLETS, 5 MG AND 10 MG**

| Product                             | NDC Number   | UPC Code       | Lot Numbers | Expiration Date | Distribution Date   | Quantity to be returned |
|-------------------------------------|--------------|----------------|-------------|-----------------|---------------------|-------------------------|
| Asenapine Sublingual Tablets, 5 mg  | 42794-016-10 | 3 4279401610 3 | 2012501     | AUG 2022        | DEC 2020            |                         |
|                                     | 42794-016-10 | 3 4279401610 3 | 2012601     | AUG 2022        | DEC 2020 – JAN 2021 |                         |
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|                                     | 42794-016-10 | 3 4279401610 3 | 2100701     | AUG 2022        | APR 2021            |                         |
| Asenapine Sublingual Tablets, 10 mg | 42794-017-10 | 3 4279401710 0 | 2012801     | AUG 2022        | DEC 2020            |                         |
|                                     | 42794-017-10 | 3 4279401710 0 | 2012901     | AUG 2022        | DEC 2020 – JAN 2021 |                         |
|                                     | 42794-017-10 | 3 4279401710 0 | 2013001     | AUG 2022        | JAN 2021 – FEB 2021 |                         |
|                                     | 42794-017-10 | 3 4279401710 0 | 2100101     | NOV 2022        | FEB 2021            |                         |
|                                     | 42794-017-10 | 3 4279401710 0 | 2100501     | AUG 2022        | FEB 2021 – APR 2021 |                         |

**Please check ALL appropriate boxes.**

I have read and understand the recall instructions provided in the April 16, 2021 letter.

I have checked my stock and have quarantined inventory consisting of \_\_\_\_\_ <units or cases>.

Indicate disposition of recalled product:

returned (specify quantity: \_\_\_\_\_, date: \_\_\_\_\_ and method : \_\_\_\_\_) /held for return;

destroyed (specify quantity: \_\_\_\_\_, date: \_\_\_\_\_ and method : \_\_\_\_\_);

I would like to receive a pre-paid return label.

Total number of Call Tags (Number of Boxes you will be returning): \_\_\_\_\_

Return product to:

Eversana Life Science Services  
 c/o SigmaPharm Recall  
 ATTN: Returns Department  
 4580 S. Mendenhall Rd.  
 Memphis, TN 38141

Note: A prepaid shipping label will be sent to the email address provided below. The email will be coming from EVERSANA within 5 business days. Please check the spam folder if you do not see it in your inbox. **Please note the FedEx link is only valid for 10 days.**

Sigmapharm Laboratories, LLC • 3375 Progress Drive • Bensalem, PA 19020 • USA  
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I have or will contact those further distributed to. This recall is to the **wholesale level**.

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       grocery corporate headquarters     food service/restaurant
- repacker                       manufacturer       pharmacy                                       retail
- hospital/medical facility       hospital pharmacies       medical laboratory
- Other: \_\_\_\_\_

**\*Wholesaler required field**

Contact Information:

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title: \_\_\_\_\_ Tel Number: \_\_\_\_\_

Email: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

\*Debit Memo \_\_\_\_\_

**\*\*Pharmacy required fields**

\*\*Wholesaler: \_\_\_\_\_ \*\*WholesalerAccount#: \_\_\_\_\_

\*\* Pharmacy DEA # \_\_\_\_\_

Please send this completed recall response form to: Email [DDNRegulatory@Eversana.com](mailto:DDNRegulatory@Eversana.com) and [SigmaPharmCS@Eversana.com](mailto:SigmaPharmCS@Eversana.com) or Fax 1-414-434-6695

If you have any questions related to the return of these products, contact Customer Service at 1-855-206-7815, option 1 on Monday through Friday between 8 am – 7 pm CST. If you have any other questions related to this recall, please contact Sigmapharm's Sales & Marketing Department: Mr. McKee Moore (at 215-352-6655, Ext 258) or Mr. Robert Citrino (at 215-352-6655, Ext 259).

Sincerely,

Prakash Patel  
Senior Vice President, Quality Operations Division  
Sigmapharm Laboratories, LLC