URGENT RECALL of Venlafaxine Extended-Release Tablets, 150 mg (Retail Level)

01/16/25

From:
Rama Joga Eranki
Sr. Vice President, Quality & Compliance
Appco Pharma, LLC
262 Old New Brunswick Road, Suite N,
Piscataway, NJ 08854

Dear Retailer,

This is to inform you of a product recall involving **Venlafaxine Extended-Release Tablets, 150 mg, White to off white, round shaped coated tablet, debossed with "AC 406" on one side and plain on other side, UPC#343598943909, Lot# 2402101UR**
See enclosed product label (Container label and Pack insert) in attachment#1a &1b for ease in identifying the product at retail level.

This recall has been initiated due to no embossing details (No Tablet ID) on both sides of few tablets. Consumption of this product does not pose any risk to safety or health. We reassure you that despite this oversight, the safety and efficacy of the product remain uncompromised.

Immediately examine your inventory and quarantine the subject product to recall. In addition, if you may have further distributed this product, please identify your customers/retail pharmacies 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. Promptly complete the attached recall stock response form even if you have **no** product to return.

Mode of prepaid return label receipt can be specified according to your preferences. (Email/Address). Typically, when opting for prepaid return labels, you can choose to receive them electronically via email or have physical copies mailed to your address. Please ensure to provide valid email address/mailing address to receive prepaid return labels in a timely manner

This recall shall be carried out at retail level. Your cooperation in promptly returning the product is greatly appreciated.

Please complete and return the enclosed response form (recall stock response form) as soon as possible to recallinfo@appcopharma.com. For further inquiries, contact us at 732-253-7735 X 119 (M-F 9:00AM -5:00 PM).

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting Program either online, by regular mail or by fax:
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.

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

Sincerely,

01/16/2025

Rama Joga Eranki
Sr. Vice President, Quality & Compliance
Appco Pharma, LLC

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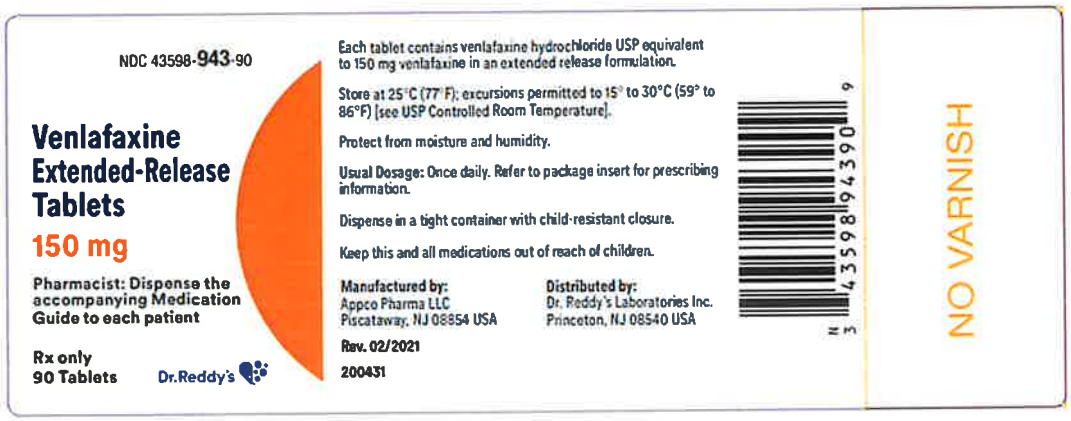
Attachment-1a

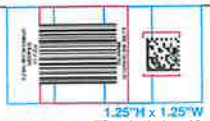
Product Container label



9.125" 17.0" W .625" .625" 6.625"

24.0"L

Width: 17.0"
Length: 24.0"
Fold: 1.25" x 1.25"



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1.25"H x 1.25"W

24.0"L

Medication Guide

Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with your or your family member's antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines. **Talk to your, or your family member's, healthcare provider about:**

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illness

Who should not take Venlaflaxine Extended-Release Tablets?

- take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- Do not take an MAOI within 7 days of stopping venlaflaxine extended-release tablets unless directed to do so by your physician.
- Do not start venlaflaxine extended-release tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?

1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
   - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
   - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
   - Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood
- Visual Problems: Eye pain, change in vision, swelling or redness around eye

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.**
  Stopping an antidepressant medicine suddenly can cause other symptoms
- **Visual Problems.** Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.

  Especially tell your healthcare provider if you take:
  - medicines to treat migraine headaches known as triptans
  - tricyclic antidepressants
  - lithium
  - tramadol, fentanyl, meperidine, methadone, or other opioids
  - tryptophan
  - buspirone
  - amphetamines
  - St. John's Wort
  - phentermine
  - other medicines containing desvenlafaxine or venlafaxine
  - medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.
- **Sexual problems (dysfunction).** Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including venlafaxine extended-release tablets, may cause sexual problems.

  Symptoms in males may include:
  - Delayed ejaculation or inability to have an ejaculation
  - Decreased sex drive
  - Problems getting or keeping an erection

  Symptoms in females may include:
  - Decreased sex drive
  - Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with venlafaxine extended release tablets. There may be treatments your healthcare provider can suggest.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This Medication Guide has been approved by the U.S. Food and Drug Administration for all antidepressants.

Manufactured by:
Agena Pharma LLC
Piscataway, New Jersey 08854

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Dr.Reddy's

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venlafaxine hydrochloride