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www.AurobindoUSA.com

Aurobindo Pharma USA, Inc. on behalf of AuroHealth, issues Voluntary Nationwide Recall of one (1) Lot of Healthy Living Over the Counter (OTC) Migraine Relief: Acetaminophen 250mg; Aspirin 250mg; Caffeine 65mg tablets, due to missing manufacturer label

Aurobindo Pharma USA, Inc.: Contact 1-866-850-2876 (Option 2)

Recall being handled by Qualanex: Contact 1-888-504-2014

FOR IMMEDIATE RELEASE – July 18, 2024 – East Windsor, New Jersey.
Aurobindo Pharma USA, Inc., on behalf of AuroHealth, is voluntarily recalling one lot (refer table below) of Healthy Living Migraine Relief, Acetaminophen 250mg, Aspirin (NSAID) 250mg & Caffeine 65mg tablets, to the consumer level as sold through Amazon to known within the US market due to the product missing the manufacturer label.

NDC No.	Product Name, strength, and pack	Lot number	Expiry
58602-882-21	Acetaminophen 250mg; Aspirin 250mg; Caffeine 65mg tablets – 100ct bottles	AC2523005A	June-2025

Risk Statement: Amazon customers having purchased the above product will have a white unlabeled bottle from the Manufacturer (AuroHealth) bearing only an Amazon identifying sticker, as shown below. As a result, the product lacks the required Over the Counter (OTC) labeling information, drug facts and patient usage information. There is significant risk of misuse which could result in permanent liver damage if consumers exceed the recommended dose, combine use with excessive consumption of alcohol or are allergic to the active ingredient which could be life-threatening. To date, Aurobindo has not received any reports of adverse drug events that are confirmed related to this recall.

Aurobindo Pharma USA, Inc. began shipping of the subject batch to customers nationwide in January 2024. AuroHealth Over the Counter (OTC) bottle(s) with no label affixed to the bottle (i.e. Brite Stock) was inadvertently supplied to Amazon, who then further placed an Amazon sticker with the product name and distributed the OTC product (without the Agency filed and approved label) to end users.

Healthy Living Migraine Relief, Acetaminophen, Aspirin (NSAID) & Caffeine tablets are indicated for temporarily relief of minor aches and pains due to: headache, a cold, arthritis, muscular aches, toothache, premenstrual and menstrual cramps.

Aurobindo Pharma USA, Inc. • 279 Princeton Hightstown Road • East Windsor, NJ 08520-1401
{phone}866.850.2876 • {fax}732.355.9449

As per the product information leaflet, Healthy Living Migraine Relief, Acetaminophen, Aspirin (NSAID) & Caffeine tablets are “White to off-white, capsule shaped, biconvex film-coated tablet debossed with “T” on one side and “57” on the other side. The product is packaged in 100 count bottles

The product label affixed by Amazon is as shown below:

Qualanex, on behalf of Aurobindo Pharma USA, Inc., will be notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Aurobindo Pharma USA, Inc. is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Aurobindo Pharma USA, Inc. at:

- 1-866-850-2876 (Option 2), 24 hours per day, 7 days per week; or
- pvg@aurobindousa.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Any general questions regarding the return of this product please contact Qualanex at 1-888-504-2014 (live calls received 7:00 am to 4:00 pm M-F CST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch 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 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 conducted with the knowledge of the U.S. Food and Drug Administration.

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