Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-016-CG
April 1ST , 2024

FDA announced that East Windsor, New Jersey, Eugia US LLC (f/k/a AuroMedics Pharma LLC) has initiated a voluntary recall of lot number 3MC23011 of Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial) - 10mL Vial to the consumer level due to a customer product complaint for the presence of white particles floating inside of the vial

RECOMMENDATIONS

1. Eugia US LLC (f/k/a AuroMedics Pharma LLC) is notifying its distributors by recall letters and is arranging for the return/replacement of all recalled products. Wholesalers, hospitals, pharmacies, institutions, and doctors with an existing inventory of the recalled product lot should discontinue use, stop distribution and quarantine the product immediately. If you have further distributed the recalled product lot, notify your accounts and/or any additional locations which may have received the recalled product. Hospitals/Institutions should inform Healthcare Professionals in your organization of this recall.
2. Consumers with medical questions regarding this recall or to report an adverse event can contact Eugia US LLC from 8:00 am to 5:00 pm (EST) Monday - Friday at: 1-866-850-2876, Option 2pvg@aurobindousa.com.
3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
4. If you have any general questions regarding the return of this product, please contact Qualanex at 1-800-505-9291 or email recall@qualanex.com (live calls received 7:00 am to 4:00 pm M-F CST).
5. Review your inventory to identify existence of recalled products.
6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Eugia US LLC (f/k/a AuroMedics Pharma LLC) Issues Voluntary Nationwide Recall of Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial) Due to Presence of White Particles

SUMMARY:

Company Announcement Date:	March 28, 2024
FDA Publish Date:	March 28, 2024
Product Type:	Drugs
Reason for Announcement:	Device & Drug Safety – Presence of Particulate Matter
Company Name:	Eugia US LLC
Brand Name:	Eugia US LLC
Product Description:	Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial)

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE –March 22, 2024– East Windsor, New Jersey, Eugia US LLC (f/k/a AuroMedics Pharma LLC) has initiated a voluntary recall of lot number 3MC23011 of Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial) - 10mL Vial to the consumer level due to a customer product complaint for the presence of white particles floating inside of the vial.

Risk Statement: Administration of an injectable product that contains particulate matter may result in local irritation or swelling. If the particulate matter reaches the blood vessels or is injected intravascularly it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Eugia US LLC has not received any reports of adverse events related to this recall.

Methocarbamol injection USP 1000 mg/10 mL (100mg/mL), is used as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. It is packaged in 10 mL and packed as 25 (vials) X 04 (Printed E-Flute cartons) X 01 (Shipper) with NDC code as 55150-223-10. Eugia US LLC shipped the entire lot to wholesalers nationwide from Jan 12, 2024, through Jan 16, 2024.

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The product can be identified by product name on carton and vial label and with lot number 3MC23011 and Exp. Date: Nov 2026 (NDC 55150-223-10) (See enclosed vial label).

The product label is as shown below:

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Consumers with medical questions regarding this recall or to report an adverse event can contact Eugia US LLC from 8:00 am to 5:00 pm (EST) Monday - Friday at:

- 1-866-850-2876 Option 2
- pvg@aurobindousa.com

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

If you have any general questions regarding the return of this product, please contact Qualanex at 1-800-505-9291 or email recall@qualanex.com (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 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

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