Company Announcement

> When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

MarcasUSA, LLC Issues Voluntary Nationwide Recall of Pasta De Lassar Andromaco Skin Protectant 25% Zinc Oxide 60g Due to Potential Contamination

For Immediate Release

March 29, 2018

Contact

Consumers

✉ **info@pastadelassar.com (mailto:info@pastadelassar.com)**
☎ 1-800-428-9489

Announcement

MarcasUSA, LLC and Industria Farmacéutica Andromaco, S.A. de C.V. is voluntarily recalling four lots of Pasta De Lassar Andromaco Skin Protectant, 25% zinc oxide to the retail level. FDA analysis of this product confirmed that Pasta De Lassar Andromaco is contaminated with high levels of yeast, mold, and bacteria. The specific lot associated to the positive findings was never sold in the US. However, due to the amount and type of contamination the remaining four lots in the US market are being recalled out of an abundance of caution.

Use of the contaminated product could result in an increased risk of infection. To date, MarcasUSA has not received any reports of adverse events related to this recall.

PASTA DE LASSAR ANDROMACO® brand of over-the-counter (OTC) skin protectant 25% zinc oxide is indicated for treatment and prevention of diaper rash and other minor skin irritations. The affected product includes that following lots and expiration dates:

Description	Item Code	Lot Numbers	Exp Date
PASTA DE LASSAR ANDROMACO® Skin Protectant, 25% zinc oxide Topical cream, 60-gram tube	UPC #851357003004 NDC #75940-111-60	17LP117 15PL041 15PL040 15PL039	10-2020 04-2018 04-2018 05-2018

The product is packaged in 60 gram tubes sold in individual boxes (UPC #851357003004, NDC #75940-111-60). The product was distributed Nationwide via wholesale, retail and internet. MarcasUSA, LLC is notifying its distributors and customers by direct contact and is arranging for return of all recalled products. Consumers that have the product which is being recalled should stop using and return it to the place of purchase or discard it.

Distributors and retailers that have Pasta De Lassar Andromaco® which is being recalled should return to place of purchase (wholesaler or distributor).

Consumers with questions regarding this recall can contact MarcasUSA by phone at +1-800-428-9489 or by e-mail **info@pastadelassar.com (mailto:info@pastadelassar.com)** on Monday - Friday from 8am to 5pm, PST. 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.

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 (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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 conducted with the knowledge of the U.S. Food and Drug Administration.

Link to **Spanish Version (/Safety/Recalls/ucm603340.htm)**

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