Eisai Inc.
100 Tice Blvd., Woodcliff Lake, NJ 07677
Phone 201-692-1100

hhc
human health care

January 13, 2016

Subject: Shortage of US-approved Panretin gel (alitretinoin) 0.1%; Distribution of EU-approved Panretin gel

Dear Health Care Provider,

There is a manufacturing issue with the U.S.-approved Panretrin gel tubes, which has resulted in a shortage of this product in the U.S. We are working closely with the U.S. Food & Drug Administration to address the manufacturing issues for the U.S.-approved Panretin gel product.

In order to alleviate the shortage of Panretin gel in the U.S., FDA is allowing the sale of Panretin gel tubes approved for use in the European market ("EU-approved Panretin gel"). The U.S. FDA has confirmed that the EU-approved Panretin gel meets the manufacturing release specifications required by the FDA for the U.S.-marketed product.

Please note that there are differences in the labeling for the Panretin gel tubes between the U.S.-approved and the EU-approved products. A copy of the FDA-approved prescribing information is being distributed with the European Panretin gel. Please refer only to the U.S.-approved package insert for full prescribing information. Storage conditions and use are the same as that of the U.S. Product. Panretin gel is for topical use only, not for ophthalmic use. Store at 25°C (77°F) with excursions permitted to 15-30°C (59-86°F). Keep out of reach of children.

U.S. FDA-approved Indication

Panretin gel is indicated for topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma (KS). Panretin gel is not indicated when systemic anti-KS therapy is required (for example, when more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement). There is no experience to date using Panretin gel with systemic anti-KS treatment.

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For reporting of adverse events and more information

You are encouraged to report any adverse effects or medication issues resulting from the use of this drug to the Eisai Medical Affairs Department at 1-888-274-2378.

Adverse effects or quality problems experienced with the use of this product may also 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.htm/report,
- Regular mail or fax: Download the form www.fda.gov/MedWatch/getforms.htm or call 1-800-FDA-1088 to request a form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-332-1078.

We are committed to helping address patients' unmet needs through our corporate *human health care* mission. If you have questions or concerns regarding this product, please call the Eisai Medical Affairs Department at 1-888-274-2378.

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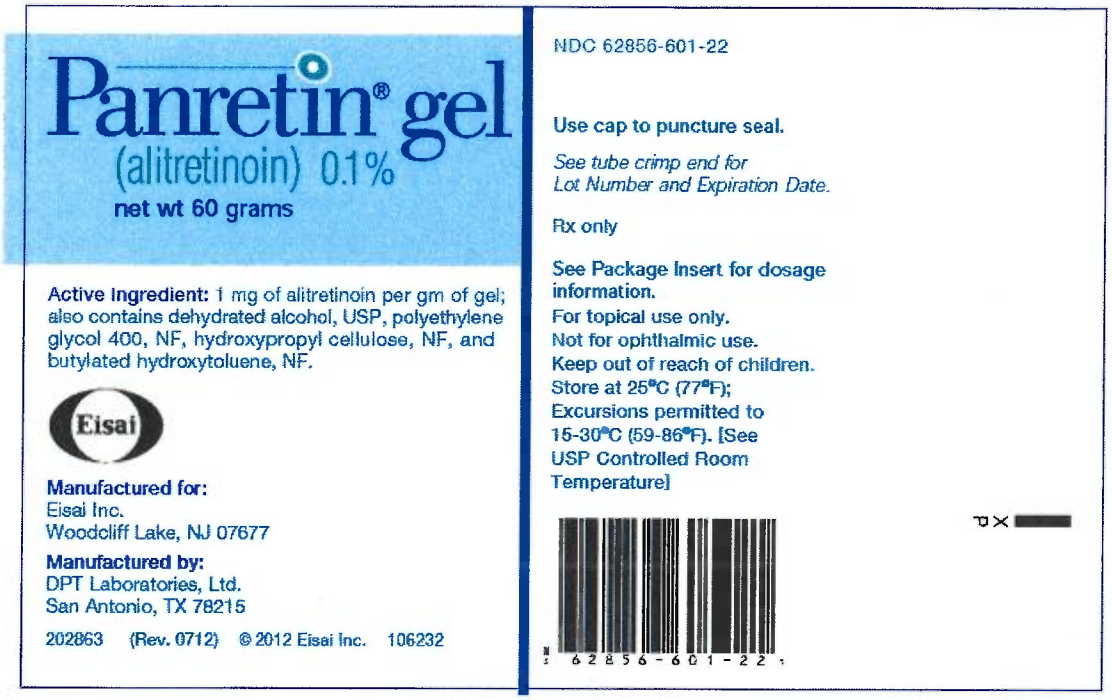
U.S. Tube Label:



EU Tube Label: