ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

May 14, 2019

Urgent: Novartis Pharmaceuticals Corportation Issues a Voluntary Recall of Three Lots of Promacta® (eltrombopag) 12.5mg for Oral Suspension

Dear ASD Healthcare Customer:

Novartis Pharmaceuticals Corporation (Novartis) is initiating a voluntary recall of three lots of Promacta 12.5 mg for Oral Suspension. The affected lot information is listed below.

Novartis initiated this recall because of a risk of potential peanut flour contamination. Based on a detailed risk assessment and a comprehensive investigation performed, the risk of cross contamination between peanut flour and Promacta 12.5mg for Oral Suspension is considered low, but cannot be ruled out. Therefore, due to patient safety concerns, Novartis is recalling Promacta 12.5mg for Oral Suspension. **No other Promacta formulation or dosage strengths are impacted as they are not manufactured at this facility.**

Novartis provided the following affected lot information:

Product Description	Lot #	Expiration Date
Promacta for Oral Suspension	8H57901589	09/2020
Promacta for Oral Suspension	9H57900189	12/2020
Promacta for Oral Suspension	9H57900289	12/2020

To reduce any risk, we ask for your cooperation in taking the following action:

- Please examine your inventory immediately to determine if you have any impacted product in stock.
- If you do have inventory of any of the recalled lot numbers, **please stop distribution and dispensing of the product and quarantine impacted units**.
- **Contact Stericycle at 866-918-8772 for a recall packet. You will be able to use this packet to promptly return any units** on hand to:

  Stericycle Inc.
  2670 Executive Drive, Suite A
  Indianapolis, Indiana 46241

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Novartis also asks that you assist in notifying patients who may have received the impacted lots of Promacta 12.5mg for Oral Suspension. As there is no immediate resupply of Promacta 12.5mg for Oral Suspension at this time, patients should contact their physician. Novartis is working with the contract manufacturer for solutions. **Patients should also contact Stericycle at 866-918-8772 for a recall packet. Stericycle will assist them with any questions on reimbursement.**

Any medical related inquiries should be directed to Novartis at 888-NOW-NOVA (888-669-6682). Report any adverse events to Novartis by calling 888-NOW-NOVA (888-669-6682) or e-mailing usdrugsafety.operations@novartis.com, or to the FDA at www.fda.gov/medwatch/report.htm

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273.**

NOVARTIS

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936

URGENT DRUG PRODUCT RECALL

PROMACTA® (eltrombopag) 12.5mg for Oral Suspension

May 13, 2019

Dear Wholesaler/Pharmaceutical Buyer:

RECALLING FIRM:

Name	Address	City	State	Zip
Novartis Pharmaceuticals Corporation	One Health Plaza	East Hanover	NJ	07936

REASON and RISK:

Novartis Pharmaceuticals Corporation is voluntarily recalling three lots of Promacta 12.5mg for Oral Suspension. The lots are being recalled because of a risk of potential peanut flour contamination.

Based on a detailed risk assessment and a comprehensive investigation performed, the risk of cross contamination between peanut flour and Promacta 12.5mg for Oral Suspension is considered low, but cannot be ruled out. Therefore, due to patient safety concerns, Novartis is recalling Promacta 12.5mg for Oral Suspension. No other Promacta formulation or dosage strengths are impacted as they are not manufactured at this facility.

Peanut is a known food allergen. Potential cross contamination with peanut flour, even in traces, can lead to hypersensitivity reaction in a population of patients with an unknown or known sensitivity to peanut antigen, including medically significant anaphylactic reaction, which can potentially be fatal. This can be a serious concern from patient safety aspect.

This notification applies ONLY to Promacta 12.5mg for Oral Suspension and DOES NOT apply to Promacta Tablets

Impacted Promacta 12.5mg for Oral Suspension Lot Numbers:

Product Description	NDC Number on Carton	NDC Number on Packet	Lot Number	Expiration Date	Distribution Dates
Promacta for Oral Suspension	0078-0972-61	0078-0972-19	8H57901589	09/2020	1/2/19 – 2/11/19
Promacta for Oral Suspension	0078-0972-61	0078-0972-19	9H57900189	12/2020	2/11/19 – 4/17/19
Promacta for Oral Suspension	0078-0972-61	0078-0972-19	9H57900289	12/2020	3/6/19 – 4/2/19

THIS RECALL SHOULD BE CARRIED OUT TO THE PATIENT LEVEL

ACTION BY WHOLESALER/PHARMACEUTICAL BUYER:

Please examine your inventory immediately to determine if you have any impacted product in stock. If you do have inventory of any of the recalled lot numbers, **please stop distribution and dispensing of the product and quarantine impacted units. Promptly return any units you have along with the packing slip (using the prepaid UPS label) to**:

Stericycle Inc.
2670 Executive Drive, Suite A
Indianapolis, Indiana 46241

If you have any questions, please contact Trade Operations at 1-800-526-0175.

In addition, please disseminate this information immediately to your customers who have received Promacta 12.5mg for Oral Suspension.

ACTION BY PHARMACIST:

Please examine your inventory immediately to determine if you have any impacted product in stock.

If you do have inventory of any of the recalled lot numbers, **please stop distribution and dispensing of the product and quarantine impacted units. Contact Stericycle at 866-918-8772 for a recall packet. You will be able to use this packet to promptly return** any units on hand to:

Stericycle Inc.
2670 Executive Drive, Suite A
Indianapolis, Indiana 46241

PATIENT NOTIFICATION:

We also ask that you assist us in notifying patients who may have received the impacted lots of Promacta 12.5mg for Oral Suspension. As there is no immediate resupply of Promacta 12.5mg for Oral Suspension at this time, patients should contact their physician. Novartis is working with the contract manufacturer for solutions. Patients should also contact Stericycle at 866-918-8772 for a recall packet. Stericycle will assist them with any questions on reimbursement.

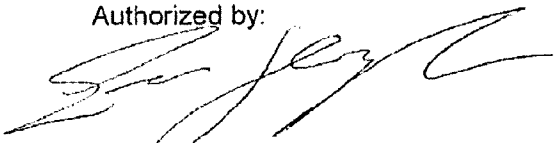
Any medical related inquiries should be directed to Novartis at 888-NOW-NOVA (888-669-6682). Report any adverse events to Novartis by calling 888-NOW-NOVA (888-669-6682) or e-mailing usdrugsafety.operations@novartis.com, or to the FDA at www.fda.gov/medwatch/report.htm

OTHER INFORMATION:

Further information about this recall is available at 888-NOW-NOVA (888-669-6682).

Credit for wholesaler and pharmacy returns will be issued at the current Novartis Pharmaceuticals Corporation Wholesale Acquisition Cost (WAC) selling price. Reimbursement for handling costs will be issued at $1.90 per each carton.

Authorized by:



Emma Harrington
Head, Novartis Country Quality, US