



Sandoz Inc.
100 College Road West
Princeton, NJ 08540
www.us.sandoz.com

December 07, 2021

URGENT DRUG RECALL:
CLINDAMYCIN AND BENZOYL PEROXIDE GEL 1% / 5%
RE-ISSUED TO RETAIL LEVEL

Dear Valued Customer:

The purpose of this letter is to inform you that Tolmar Inc. has initiated a voluntary recall of three lots of Clindamycin and Benzoyl Peroxide Gel as listed below to the retail level. Sandoz Inc. ("Sandoz") as the distributor of the product, has been requested to notify our customers of this recall.

Product Name	NDC Nbr	Lot Nbr	Exp. Date	Manufacturing Date
Clindamycin and Benzoyl Peroxide Gel 1%/5% (25g Jar)	0781-7263-68	11557C1	02/2022	August 19, 2020
Clindamycin and Benzoyl Peroxide Gel 1%/5% (25g Jar)	0781-7263-68	11552B1	04/2022	October 20, 2020
Clindamycin and Benzoyl Peroxide Gel 1%/5% (25g Jar)	0781-7263-68	12206A1	11/2022	May 28, 2021

The lots were distributed October 2020 – September 2021.

This recall has been initiated because stability testing has found Lot 11557C1 to be Out of Specification (OOS) based upon Tolmar's stability testing of the lot obtained at the 12-month timepoint for clindamycin phosphate in the reconstituted product. Three samples for Lot 11557C1 were tested resulting in 106.1%, 108.8%, and 111.5% of label claim, with one result exceeding the established specification 95.0% – 110.0%. Following determination of the above, all unexpired Clindamycin and Benzoyl Peroxide Gel 1%/5% (25g jar) lots were evaluated and based on the results, Lots 11557C1, 11552B1 and 12206A1 are included within the scope of this recall.

The adverse skin reaction would likely initially present as irritant contact dermatitis (i.e. localized inflammation) that would likely be noticeable by users prior to becoming a serious medical problem. The risk of harm due to the OOS Clindamycin Assay in the Constituted Product for the indication of acne vulgaris, would be low. As this is a topical product, this risk is considered low from a medical perspective.

WHOLESALE ACTION:

Please take the following steps:

1. Immediately stop distribution of Lots 11557C1, 11552B1, and 12206A1 and quarantine any quantities of these lots remaining in your inventory.
2. If you have further distributed product from Lots 11557C1, 11552B1, and 12206A1, please contact those customers immediately and notify them of this recall. This letter can be used to supplement your notification.
3. Conduct a physical count of product belonging to Lots 11557C1, 11552B1, and 12206A1 in your inventory and record the number on the enclosed business reply card and packing slip.
4. **Please complete and return the postage-paid business reply card even if you do not have any units of recalled lots 11557C1, 11552B1, and 12206A1 in your inventory.**
5. Return the recalled product and the packing slip, using the prepaid UPS shipping label, to the address below:

**Sedgwick Brand Protection
2670 Executive Drive
Indianapolis, Indiana 46241**

PHARMACY ACTION:

1. Immediately stop distribution of Lots 11557C1, 11552B1, and 12206A1 and quarantine any quantities of these lots remaining in your inventory.
2. Pharmacists should contact Sedgwick directly by phone at 888-216-6302 or email sandoz7306@sedgwick.com to request a recall packet. Representatives are available Monday – Friday, 8:00am – 5:00pm ET.

The recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please report any adverse events by calling Sandoz at (800) 525-8747. Customer service agents are available Monday – Friday from 8:30 am to 5:00 pm ET. Adverse events can also be reported to FDA online at www.fda.gov/medwatch/report.htm.

Do not include non-Sandoz items or other Sandoz labeled items in your shipment. Any product returned that is not associated with this recall will be destroyed and no credit issued.

For product or credit questions regarding Lots 11557C1, 11552B1, and 12206A1 please follow your normal credit process. For questions about the recall process or to request additional recall packets, please call Sedgwick directly by phone at 888-216-6302 or email sandoz7306@sedgwick.com. Representatives are available Monday – Friday, 8:00 am – 5:00 pm ET.

We appreciate your immediate attention and cooperation and apologize for any inconvenience caused by this action.

Sincerely,
Sanchez
Julia

Digitally signed by
Sanchez Julia
Date: 2021.12.07
11:47:24 -05'00'

Julie Sanchez
Head, Novartis Country Quality US