



PRINT

2021-0027557

Sun Pharma

Product Complaint

Product	Levulan Kerastick Topical Solution
Request Via	Non-Representative
Created	16-Feb-2021
Language	English
Communication Mode	Phone
Case Status	Completed (19-Feb-2021)

Products

Product	Quantity	Expiration Date	Lot Number
Levulan Kerastick Topical Solution	1	30-Apr-2022	AA36972

Sample Return

Tracking Number	Sample Available	Date Sample Requested	Date Sample Returned
1Z1VX6768495391386	Yes	19-Feb-2021	

Contacts

Primary	Name	Address	Phone Fax Email	Reporter Type Occupation HCP?	Institution
✓	Michelle R	575 Coal Valley Road STE 360 Clairton, Pennsylvania 15025 United States	(412) 466-9400	Company Representative Medical Representative	The Skin Surgery Center

Description of Problem

Sun Pharma PC for Levulan Kerastick

Description of Unexpected, Undesirable Characteristic: No content present when attempting to break stick

NDC #: 67308-101-01

Please populate product details in module fields.

Number of LEVULAN KERASTICK applicators affected:(1)

Was the Levulan Kerastick carton damaged when received? No

Was there brown staining observed on the Levulan Kerastick when received? No

Were manual preparation or Kerastick Krusher preparation guidelines followed? Yes

Please describe Kerastick preparation instructions and any issues in detail: Removed stick from box, pushed side A, then side B, tried to shake the stick and nothing came out.

Please describe preparation of the treatment area before light illumination: Had to administer another stick

How long was the topical solution allowed to stay on the patient before exposure to BLU-U therapy?: N/A

Did the patient miss therapy as a result of this issue? If yes, please provide details No, used another stick

Patient's Date of Birth: 11-DEC-1944

What is the name of the supplier of KERASTICKS? Sun Pharma

Supplier account number (if applicable): 102374

Reporter Agrees to Product Retrieval?: Yes

Name, address and phone number of physician's office:

The Skin Surgery Center

575 Coal Valley Road STE 360 Pittsburgh PA 15025

412-466-9400

Quantity of KERASTICKS to be Retrieved: (1)

Within the next few days you will receive a letter and a pre-paid return envelope to return the product. To assist in our investigation, please return the product as soon as possible.

*Obtain a physical address if mailing address is a P.O. Box. UPS cannot deliver to a P.O. Box.

*Provide caller case # and our CB #

Did caller request Product Replacement or Reimbursement? Yes, replacement item requested

Pharmalucence, Inc. (formerly DUSA) will replace the product once the defective product has been returned. If the product was destroyed, the company will replace the product. Please note, though, that if a similar situation occurs in the future, please retain the product in question for return.

For questions regarding Levulan replacement and reimbursement, please contact 1-877-533-3872 Option 5.

Note to Specialist: If call is an issue with BLU-U Blue Light Photodynamic Therapy Illuminator, please ask caller to contact 1-877-533-3872 Option 5, then Option 3 for service of the machine.

Note to Specialist: If complainant is patient, ask pertinent questions only and then contact the doctor's office to fulfill the PQC script.

Notes

Date	Classification	
16-Feb-2021		
Note		
Michelle at doctor's office called Sun Pharma to report PC and request replacement be sent.		

Date	Classification	
17-Feb-2021	QC Complete	
Note		
Case Review Complete. Action Pending: [Retrieval.]		

Date	Classification	Attachment
19-Feb-2021	Attachment	LETTER_02676221.PDF
Note		
Letter To Michelle R		