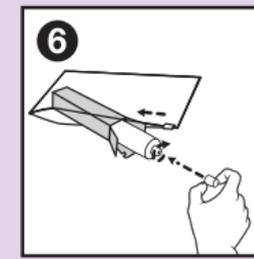
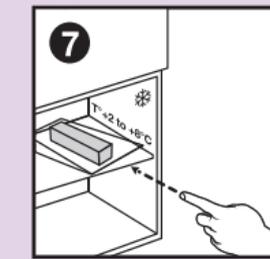


After application, wash hands with soap and water.



With clean hands, close the tube, return it to the carton and then into the transparent sealable plastic bag, and zip it closed.



Return the transparent sealable plastic bag to the refrigerator.



Patient and Caregiver instructions

LEDAGA[®] 160 micrograms/g gel chlormethine

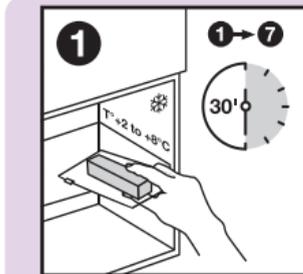


LED-UK-005

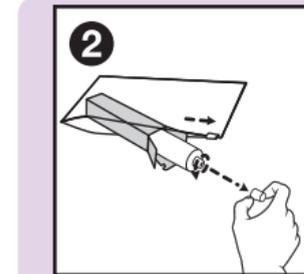
In case of direct skin contact with LEDAGA in individuals other than the patients, wash abundantly with water and contact your doctor.

The transparent sealable plastic bag supplied with LEDAGA to prevent secondary exposure and contaminations is child resistant.

Do not throw away any medicinal product or nitrile gloves used for application and ask your pharmacist.



Apply LEDAGA immediately or within 30 min after taking it out of the refrigerator.



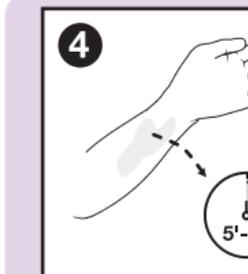
Unzip the transparent sealable plastic bag, take LEDAGA out of the carton and open the tube.



Patient
Apply a thin layer to completely dry skin.



Caregiver
Caregivers must wear nitrile gloves before applying a thin layer to completely dry skin.



4
Allow the gel to dry (5-10 min).



ESSENTRA

1224 N. Church Street
Moorestown, NJ 08057

10/19/18 7:21 AM
BS

LED-UK-005-F.ap

BLACK PMS 513 PMS 307 PMS 423

DIE LINE DARK BLUE

**COATING PLATE " - " OVERALL COATING EXCEPT WHERE NOTED
DIE# 16804**



ESSENTRA

1224 N. Church Street
Moorestown, NJ 08057

10/19/18 7:21 AM
BS

LED-UK-005-B.ap

BLACK PMS 513

DIE LINE

**COATING PLATE " - " OVERALL COATING EXCEPT WHERE NOTED
DIE# 16804**

File: LED-UK-005-Proof.pdf
 Inspection: 1 Barcode Inspect Sample
 Inspected by: Pre Press
 Inspected on: 10/19/2018 7:34 AM (UTC-04)

Status: Pass
 Product ID: LEDUK005
 Product Lot #:
 Product Name:

Patient and Caregiver instructions

LEDAGA 160 micrograms/g gel
 chlormethine

HELSINN

LED-UK-005-F.ap
 ESSENTRA
 Black Chlormethine
 Mowbray, NJ 08852
 10/19/18 7:34 AM
 BS

LED-UK-005-B.ap
 ESSENTRA
 Black Chlormethine
 Mowbray, NJ 08852
 10/19/18 7:34 AM
 BS

Barcode Results Summary	Grade A	Grade B	Grade C	Grade D	Grade F	N/A
Barcodes found: 1	1	0	0	0	0	0

File: LED-UK-005-Proof.pdf
Inspection: 1 Barcode Inspect Sample
Inspected by: Pre Press
Inspected on: 10/19/2018 7:34 AM (UTC-04)

Status: Pass
Product ID: LEDUK005
Product Lot #:
Product Name:



Decoded value:
LED-UK-005

Barcode ID: 1
Axial Non-uniformity: A (0.01)
Fixed Pattern Damage: A (4.00)
Unused Error Correction: A
Symbol Contrast: A (85.49)
Grid Non-uniformity: A (0.00)
Modulation: A
Decode: A

Grade: **A**
Type: DataMatrix
BWR: (Hor: 0.00 mm / -0.0001 inch Ver: 0.01 mm / 0.0005 inch)
Cell Size: 0.59 mm
Data Structure: N/A
Quiet Zone: A (L: A R: A T: A B: A)

File: LED-UK-005-Proof.pdf
Inspection: 1 Barcode Inspect Sample
Inspected by: Pre Press
Inspected on: 10/19/2018 7:34 AM (UTC-04)

Status: Pass
Product ID: LEDUK005
Product Lot #:
Product Name:

Inspection Parameters (Technical)

Profile Name: Essentra

Resolution: 300

Enable red light simulation: On
Smooth filter: None
Median filter: None
Open filter: None
Close filter: None
Resolution (Measurements): 300

Linear

Process: On		
Scan gap hor. (pixel columns): 2	Min. vicinity hor. (pixels): 64	
Scan gap ver. (pixel rows): 2	Min. vicinity ver. (pixels): 56	
Minimum score: 5	Edge threshold: 40	
Min. Pharma. Width (pixels): 20	Max. Pharma. Width (pixels): 600	
Min. Pharma. Height (pixels): 20	Max. Pharma. Height (pixels): 200	
Min. Pharma. Bars: 4		
Ignore quiet zone: Off	Include in Grading: Data Structure Off	Fail Grading if BWR out of the specified range: Off
Support rotation: Off	Include in Grading: Quiet Zone Off	Min. BWR (mm): -0.1
Support Negative Barcodes: Off	Include in Grading: Narrow Bar Off	Max. BWR (mm): 0.1
Ignore checksum: Off	Include in Grading: Wide To Narrow Ratio Off	

Linear Types

UPC: On	Code 11: On	Code 128 / GS1 128: On
EAN: On	Code 32: Off	MSI: On
Interleaved: On	Code 39: On	Telepen: On
GS1 Databar: On	Code 93: On	Laetus Pharma code: On
Codabar: On		

Data Matrix

Process: On	
Max. expected symbols: 3	Min. module size (pixels): 4
Scan gap (pixel columns): 8	Max. symbol size (pixels): 600
Locator effort level: 1	Max. skew angle (degrees): 15
Edge threshold: 10	
Grade NON ISO Parameters: Off	

QR

Process: On	
Scan gap hor. (pixel columns): 2	Minimum score: 5
Scan gap ver. (pixel rows): 2	Edge threshold: 40
Grade NON ISO Parameters: Off	

File: LED-UK-005-Proof.pdf
Inspection: 1 Barcode Inspect Sample
Inspected by: Pre Press
Inspected on: 10/19/2018 7:34 AM (UTC-04)

Status: Pass
Product ID: LEDUK005
Product Lot #:
Product Name:

Comments

Performed By: _____

Reviewed By: _____