	Title	Instructions for Use – Peristomal Paste	
	Revision:	B	
	Technical documentation Number	LFD-PKG-001013	

1. PRODUCT DESCRIPTION

Protective skin barrier paste

Peristomal Paste is a convenient and effective skin barrier paste, for use with colostomies, ileostomies, urostomies and fistulas. It is used to fill any uneven skin surface that affect the ability to securely attach an ostomy appliance.

2. INTENDED PURPOSE

Peristomal Paste is intended for use as a skin barrier paste, to fill any uneven skin surfaces that affect the ability to securely attach an ostomy appliance.

2.1 INTENDED POPULATION

The product may be used on individuals with any of the aforementioned conditions.

2.2 INTENDED USER

The intended users are health care professionals, caregivers and patients in a hospital or home environment.

3. INDICATIONS

Peristomal Paste is indicated as a skin barrier paste for use with colostomies and ileostomies, urostomies and fistulas. It is used to fill any uneven skin surface that affect the ability to securely attach an ostomy appliance.

4. CONTRAINDICATIONS/SAFETY INFORMATION

- Do not use on babies under 12 weeks old.

5. WARNINGS




- Do not use if the tube is damaged or open before use.
- For external use only.
- Do not apply to cuts or open wounds or damaged skin.
- Contains alcohol.
- May sting slightly when applied.
- Should skin irritation occur, contact your doctor or another health professional.

6. INFORMATION FOR USE

Method of Application:

Peristomal Paste can be applied with a moistened finger around the stoma, filling in the uneven spaces in the skin. that affect the ability to securely attach an ostomy appliance. After having adapted the base plate or flange to the size and shape of the stoma, place the base plate directly on the paste that has been applied to the skin.

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Press the wafer down around the stoma in such a way that the paste is distributed under the wafer.

Method of Removal:

The paste is easily removed 48 hours after application. If removing the paste before this time, use warm water to remove it. It is not necessary to remove all the paste from the skin prior to a further application. The residue paste may be left in order to avoid possible irritation and the new paste applied over this residue. After use, close the tube securely.

Composition:

Contains Butyl monoester of PVM/MA

7. CLINICAL BENEFIT / SPECIAL NOTES

Prevents leakages that cause skin irritations by creating an effective seal for increased security. The paste is easy to spread and is ideal for uneven skin surfaces.




8. STORAGE

Store dressings at ambient temperature and humidity, away from direct sunlight.

9. DISPOSAL

Can be disposed based on the hospital or healthcare professional advice.

10. SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
STORAGE	
	

11. PRESENTATION


A 60g aluminium tube, presented in a unit box (1 tube per box) and packed with an IFU.

12. COMPLAINTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 3349586.

RELEASE

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13. REVISION HISTORY

CHANGE HISTORY			
Revision	Date	Change Description	ECA Originator
A	12 Jan 2023	Upload to Master Control. Update to the product description and indication to remove the indication for use on lesions and skin irregularities.	Elaine Minagh
b	08 Aug 23	Add to contraindications section do not use on babies under 12 weeks old. Remove previous history box	P Slattery

14. APPROVAL

Review and Approval	
<u>Name and Title</u>	<u>Signature and Date</u>
Elaine Minagh Regulatory Affairs Manager	Approvals captured in Master Control
Emmett McArdle R&D Manager	Approvals captured in Master Control

RELEASE