

Änderungsnummer / Change Master: C1517

Objektverknüpfungen / Object Links:

JBX 40011432 000 01 BPF Cutimed PROTECT Cream
JBX 40011432 000 02 BPF Cutimed PROTECT Cream
JBX 40011432 000 03 BPF Cutimed PROTECT Cream
JBX 40011432 000 04 Cutimed PROTECT Cream
JBX 40011432 000 05 Cutimed PROTECT Cream

Dokumentenstückliste / Document Structure:

Status		Responsible	Date
IE	in Erstellung	KRUEGAN	29.11.2016
AF	Freigabeanford.	KRUEGAN	20.12.2016
FR	freigegeben	SCHULTZB	20.12.2016
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Product Safety Data Sheet

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1.0 Name of the product	Cutimed[®] PROTECT Cream
2.0 Product description	
2.1 Description	Cutimed [®] PROTECT Cream is a barrier cream that protects the skin from bodily fluids. It protects dry, chafed, red, or irritated skin by moisturizing the skin and providing a long lasting barrier. Use of Cutimed [®] PROTECT Cream allows adhesive products to stick to the skin in the normal way.
2.2 Characteristics	<ul style="list-style-type: none">- Provides a moisture barrier- Is a barrier cream which provides skin protection from body fluids- Providing a long lasting barrier against fluids- Skin-to-skin contact does not result in skin fold adhering to skin surface (non tacking)- Does not leave a greasy film on the skin- No reduction of adhesion of medical plasters- Rub in with little friction- Temporarily resists wash-off- Highly concentrated so little goes a long way- Dries rapidly (penetrates fast to the skin)- Viscosity - thin cream- Solution is homogenous when dispensed- pH balanced- Breathable- Perfume-free- Non-tacking- Is moistening- Performs the same or better than Cavilon concerning barrier properties and adhesive force back

2.3 Intended use	Cutimed® PROTECT Cream protects skin at risk from damage and irritation, particularly suitable with incontinence. Cutimed® PROTECT Cream safeguards skin from damage associated with chronic incontinence. It moisturises and protects dry skin. The cream will not impair adhesion of adhesive dressings or medical tapes.			
2.4 Instructions for use	Yes, see leaflet (JBR05924)			
2.5 CE-class GMDN - code	CE class I and rule 4 GMDN – code number: P 46206			
2.6 Duration of application / Period of use	Apply Cutimed® PROTECT Cream thinly to cover entire affected area and repeat as necessary			
2.7 Composition	White cream: Purified Water, Ethylhexyl Isononanoate, Disiloxane, Polyisobutylene, VP Eicosene Copolymer, Hydroxyethyl Acrylate / Sodium Acryloyl Dimethyl Taurate Copolymer, Butylene Glycol, Oleth-3 Phosphate, Phenoxyethanol, Hydrogenated Styrene/Isoprene Copolymer, Allantoin, Carbomer, Triethanolamine, Methylparaben, Propylparaben, Disodium EDTA			
2.8 Latex in product and packaging material	Product composition: No latex content Packaging material: No latex content			
2.9 Phthalate in product and packaging	No content of phthalate in product No content of phthalate in packaging			
2.10 Controls	Finished product: Labelling Product size Visual check			
2.11 Product range				
	Size	Packaging	Per shipper	Product code
Cutimed® PROTECT Cream	28 g	1 piece	12 boxes	72652-00
Cutimed® PROTECT Cream	90 g	12 pieces	4 boxes	72652-03
Cutimed® PROTECT Cream	2 g	10 sachets with 2 x 2 g	boxes	72652-08
2.12 Storage conditions	Cutimed® PROTECT Cream should be stored in dry and clean conditions between 5 - 30°C. Keep well closed and protected from direct sunlight and moisture.			
2.13 Shelf life/Storage time	Expiry date is printed on the packaging Shelf life: 3 years			

3.0 Safety information of Cutimed® PROTECT Cream	
3.1 Recommendations / precautions for use	If skin condition does not improve within 7 days (or worsens), consult your doctor. Keep out of reach of children. For external use only. In case of ingestion, seek medical help. Avoid contact with eyes. Cutimed® PROTECT Cream may increase the adherence of some adhesive products.
3.2 Physical & Chemical Properties	White, homogenous cream
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contra Indications	Cutimed® PROTECT Cream should not be used on skin where an infection is present or used if there is a known allergic sensitivity to the ingredients.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used
3.6 Transport Precautions	Not applicable
3.7 Handling/ Use/ Protecting Clothing	Not applicable
3.8 First Aid	a) Inhalation: Remove person to fresh air. If signs/symptoms develop, get medical attention. b) Contact with skin: No need for first aid is anticipated. c) Contact with eyes: Flush eyes with large amounts of water. If signs/symptoms persist, get medical attention. d) Ingestion: Get medical attention. Do not induce vomiting unless instructed to do so by medical personnel.
3.9 Disposal	Landfill according to local regulations
3.10 Additional Information	Not applicable

4.0 General information	
4.1 Name, address and telephone number of supplier	BSN medical GmbH Quickbornstraße 24 D-20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificate	Certificates acc. EN ISO 9001 / EN ISO 13485 (notified body: Dekra)

History

Version/Date	Page /Item	Description of Change
01/26.04.10	Set up new document	
02/19.12.16	Page 2/3/ item 2.1, 2.2 and 2.3 Page 3, item 2.11 Page 3, item 2.12 Page 3, item 2.13	General revision, adaption to new version of PFD, Add new packaging size Update Storage conditions Update shelf life