

BARRIER PROTECTANT CREAM- barrier cream ointment

Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Barrier Protectant Cream

Active ingredients

- Menthol 0.1%
- Zinc oxide 20%

Purpose

- Anorectal analgesic
- Skin protectant

Uses

A moisture barrier that provides temporary relief from skin irritations caused by •urine •diarrhea •perspiration •fistula drainage •feeding tube site leakage •wound drainage (peri-wound skin) •minor burns •cuts •scrapes •anorectal itching •chafing

Dries the oozing and weeping of poison •ivy •oak •sumac

Warnings

For external use only.

- Avoid contact with the eyes
- Stop use and contact a physician if condition worsens, symptoms last more than 7 days, or clear up and occur again within a few days.
- Keep out of reach of children
- If swallowed, get medical help or contact Poison Control Center right away.

Do not use:

- On deep or puncture wounds
- Animal bites
- Serious burns

Keep out of reach of children.

Directions

- Gently cleanse and remove any urine or fecal matter from the treatment area
- Pat dry
- Apply a generous amount of product to the affected area
- Repeat after every incontinent episode or as needed
- For peri-G tubes: •Cleanse as above •Apply thin layer •Secure with drain sponge or product as directed.

Other information

Store between 59°-86°F (15°-30°C)

Inactive Ingredients

Active aloe gel, Calamine, Chamomilla recutita (matricaria) flower extract, Cod liver oil, Disodium EDTA, Glycerin, Lanolin, Light mineral oil, Manuka honey, Methylparaben, Microcrystalline wax, Petrolatum, Propylparaben, Sodium borate, Sorbitan oleate, Tocopherol, Water

Barrier Protectant Cream Labeling

Tube Label (2 oz)

Cat: CSC-CRMBH2 Dist. by: Cardinal Health
Waukegan, IL 60085 USA 10/14
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NDC 63517-003-32

Drug Facts	
Active Ingredients	Purpose
Menthol 0.1%	Anorectal Analgesic
Zinc Oxide 20.0%	Skin protectant

Uses: A moisture barrier that provides temporary relief from skin irritations caused by: •urine •diarrhea •perspiration •fistula drainage •feeding tube site leakage •wound drainage (peri-wound skin) •minor burns •cuts •scrapes •anorectal itching •chafing. Dries the oozing and weeping of poison: •ivy •oak •sumac.

Warnings:
For external use only. •Avoid contact with the eyes •Stop use and contact a physician if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. •Keep out of reach of children •If swallowed, get medical help or contact Poison Control Center right away. **Do not use:** •On deep or puncture wounds •Animal bites •Serious burns


Directions: •Gently cleanse and remove any urine or fecal matter from treatment area •Pat dry •Apply a generous amount of product to the affected area •Repeat after every incontinent episode or as needed •For peri-G tubes: •Cleanse as above •Apply thin layer •Secure with drain sponge or product as directed.

Other Information: •Store between 15-30°C (59-86°F)

Inactive Ingredients: Petrolatum, Water, Microcrystalline Wax, Lanolin, Sorbitan Oleate, Glycerin, Light Mineral Oil, Calamine, Sodium Borate, Manuka Honey, Disodium EDTA, Aloe Barbardensis Leaf Juice, Methylparaben, Propylparaben, Chamomilla Recutita (Matricaria) Flower Extract, Tocopherol, Cod Liver Oil

BARRIER PROTECTANT CREAM

With Zinc Oxide and Menthol
Contains Manuka Honey

 **CardinalHealth**

Net Wt.
2oz (56.7g)

3/16" NO LABEL AREA3 /16"

CAP COLOR

Tube Label (4 oz)

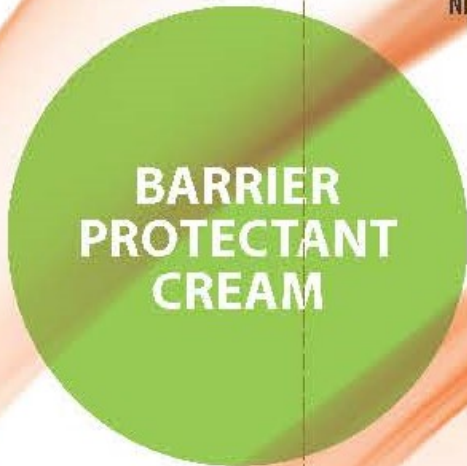
Cat: CSC-CRMBH4

Distributed by:
Cardinal Health
Waukegan, IL 60085 USA 10/14
cardinalhealth.com



NDC63517-003-31

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Drug Facts	
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Menthol 0.1%	Anorectal Analgesic
Zinc Oxide 20.0%	Skin protectant
Uses: A moisture barrier that provides temporary relief from skin irritations caused by: -urine -diarrhea -perspiration -fistula drainage -feeding tube site leakage -wound drainage (peri-wound skin) -minor burns -cuts -scrapes -anorectal itching -chafing. Dries the oozing and weeping of poison: -ivy -oak -sumac.	
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Inactive Ingredients: Petrolatum, Water, Microcrystalline Wax, Lanolin, Sorbitan Oleate, Glycerin, Light Mineral Oil, Calamine, Sodium Borate, Manuka Honey, Disodium EDTA, Aloe Barbadosis Leaf Juice, Methylparaben, Propylparaben, Chamomilla Recutita (Matricaria) Flower Extract, Tocopherol, Cod Liver Oil	

With Zinc Oxide and Menthol
Contains Manuka Honey



Net Wt.
4oz (113.4g)

3/16"	NO	LABEL	AREA 3	/16"
CAP COLOR				

Packet Labels (Box of 150)





**BARRIER
PROTECTANT
CREAM**

With Zinc Oxide and Menthol
Contains Manuka Honey



CardinalHealth

Net Wt. 0.17oz (5g)

Drug Facts

Active Ingredients	Purpose
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Menthol 0.1%	Anorectal Analgesic
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Zinc Oxide 20.0%	Skin protectant
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Uses: A moisture barrier that provides temporary relief from skin irritations caused by:

- urine •diarrhea •perspiration •fistula drainage
- feeding tube site leakage •wound drainage (peri-wound skin) •minor burns •cuts •scrapes
- anorectal itching •chafing. Dries the oozing and weeping of poison: •ivy •oak •sumac.

Warnings:

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Do not use: •On deep or puncture wounds •Animal bites •Serious burns

Directions: •Gently cleanse and remove any urine or fecal matter from treatment area •Pat dry •Apply a generous amount of product to the affected area •Repeat after every incontinent episode or as needed •For peri-G tubes: •Cleanse as above •Apply thin layer •Secure with drain sponge or product as directed.

Other Information:



SINGLE USE ONLY

Cat: **CSC-CRMBHG**

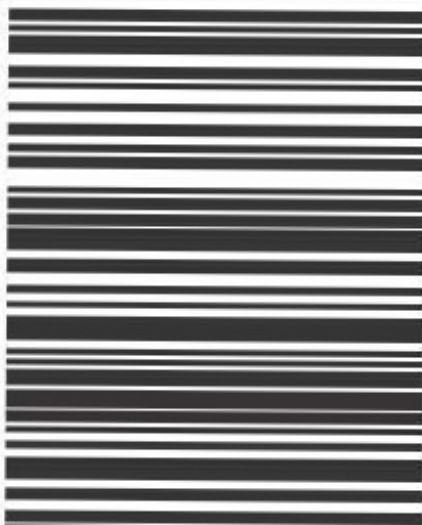
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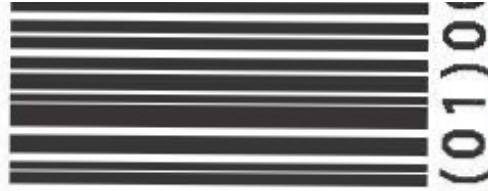
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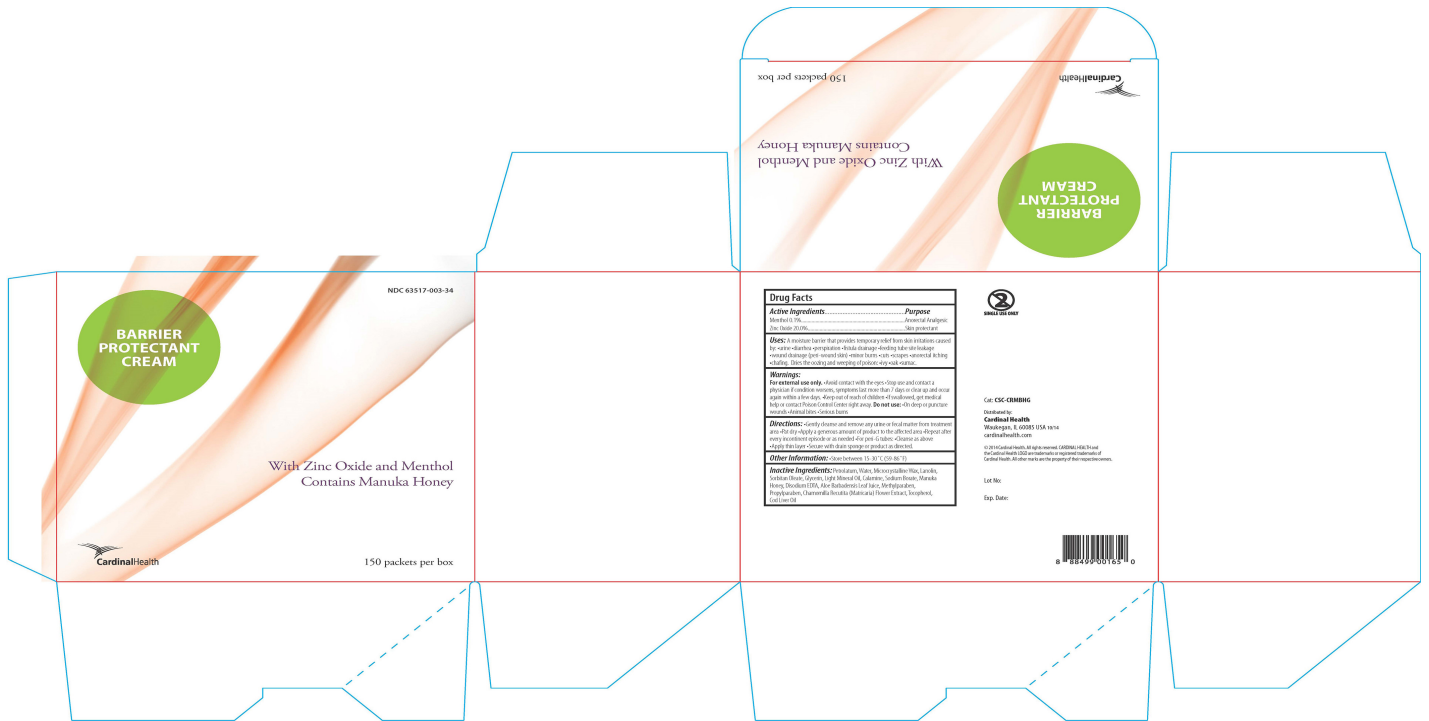
Store between 15-30°C (59-86°F)

Inactive Ingredients:
see carton for information



Lot No.:

Exp. Date.:



BARRIER PROTECTANT CREAM

barrier cream ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63517-003(NDC:51028-002)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHAMOMILE (UNII: FGL3685T2X)	
COD LIVER OIL (UNII: BBL281NWFQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
HONEY (UNII: Y9H1V576FH)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63517-003-31	113 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2015	
2	NDC:63517-003-32	57 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2015	
3	NDC:63517-003-34	150 in 1 BOX	01/15/2015	
3		5 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/15/2015	

Labeler - Cardinal Health (961027315)