

BAZA PROTECT- zinc oxide and dimethicone cream
Coloplast Manufacturing US, LLC

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.

Baza® Protect
Skin Protectant
Moisture Barrier Cream

For Skin Irritation Due to Incontinence

- Protects
- Easy to apply and remove
- Seals out wetness

Drug Facts

Active ingredients

Zinc Oxide, 12%

Dimethicone, 1 %

Purpose

Diaper Rash

Skin Protectant

Uses Helps treat and prevent minor skin irritation due to diaper rash. Helps seal out wetness.

Warnings

When using this product

- avoid contact with eyes
- not to be applied over deep or puncture wounds or lacerations.

Consult a doctor

- if condition worsens or does not improve within 7 days.

For external use only.

Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control

Center right away.

Directions

- change wet and soiled diapers promptly
- apply to affected area and gently wipe with clean, soft cloth
- apply as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged.

Inactive ingredients

BHT, cetyl alcohol, cod liver oil, EDTA, fragrance, glyceryl stearate, lanolin oil, PEG-8 stearate, PEG-40 stearate, petrolatum, propylene glycol, quaternium-15, tocopheryl acetate, tricontanyl PVP, water

See crimp for lot no. and expiration date

Manufactured by: Coloplast A/S DK-3050 Humlebaek, Denmark

Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A.

1-800-533-0464 www.us.coloplast.com

Product #1880 ©2008-7, Coloplast Corp.

Made in the U.S.A.

G8-773

PRINCIPAL DISPLAY PANEL - NET WT. 5 OZ. (142g)

NDC 11701-046-14

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Skin Protectant

Moisture Barrier Cream

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BAZA PROTECT

zinc oxide and dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11701-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	120 mg in 1 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
EDETIC ACID (UNII: 9G34HU7RV0)	
COD LIVER OIL (UNII: BBL281NWFG)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-046-22	4 g in 1 PACKET; Type 0: Not a Combination Product	06/15/2009	
2	NDC:11701-046-23	57 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2009	
3	NDC:11701-046-14	142 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/15/2009	

Labeler - Coloplast Manufacturing US, LLC (110326675)**Registrant** - Coloplast Corp (847436391)**Establishment**

Name	Address	ID/FEI	Business Operations
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE(11701-046)