BAZA ANTIFUNGAL- miconazole nitrate 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®Antifungal
Antifungal
Moisture Barrier
Antifungal
Cream

For Perineal
Skin Irritation Due to
Fungal Infection

Drug Facts

Active ingredient

Miconazole Nitrate, 2%

Purpose

Antifungal

Uses For effective treatment of jock itch. Relieves itching, scaling, irritation, redness and discomfort.

Warnings

When using this product

- avoid contact with eyes
- do not use on children under 2 years of age unless directed by a doctor.

Stop using this product and ask a doctor if irritation occurs or there is no improvement within 2 weeks.

For external use only.

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

Directions

- clean the affected area and dry thoroughly
- apply thin layer of product over affected area twice daily (morning and night), or as directed by a doctor
- supervise children in the use of this product.

Use daily for 2 weeks.

If condition persists, consult a doctor. This product is not effective on scalp or nails.

Inactive ingredients

BHT, ceteareth-6, cetyl alcohol, cod liver oil, diazolidinyl urea, fragrance, glyceryl stearate, lanolin oil, PEG-100 stearate, petrolatum, polmethoxybicyclic oxazolidine, propylene glycol, water, stearyl alcohol, tocopheryl acetate, zinc oxide

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 #1607 ©2008-7, Coloplast Corp.
Made in the U.S.A.

G8-664

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

NDC 11701-045-14

Baza® Antifungal

Antifungal

Moisture Barrier Antifungal Cream

For Perineal Skin Irritation Due to Fungal Infection

Coloplast

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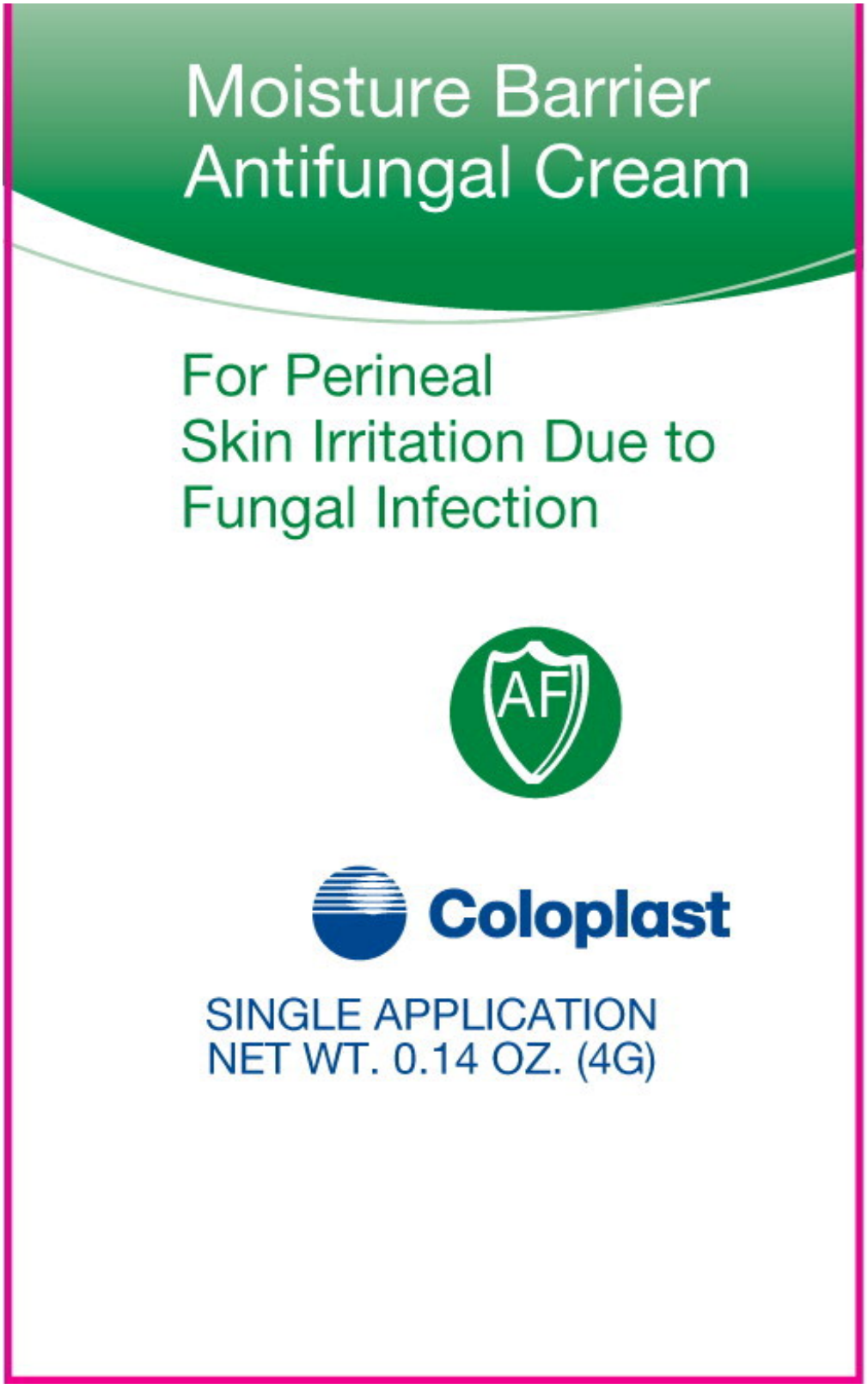
NDC 11701-045-22

Baza® Antifungal

Antifungal



BAZA ANTIFUNGAL

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11701-045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COD LIVER OIL (UNII: BBL281NWFG)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
LANOLIN (UNII: 7EV65EAW6H)	
CETEARETH-6 (UNII: 2RJS3559D3)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11701-045-22	4 g in 1 PACKET; Type 0: Not a Combination Product	06/15/2009	
2	NDC:11701-045-23	57 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2009	
3	NDC:11701-045-14	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 final	part333C	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(11701-045)