END-ITCH FOR SUNBURN- end-itch for sunburn cream
Crystal Connections, 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.

END-ITCH FOR SUNBURN

WARNINGS

For external use only

Do not use on open cuts

When using this product do not get into eyes

Do not ingest

OTC - PURPOSE SECTION

Temporarily relieves discomfort of sunburn.

OTC - ACTIVE INGREDIENT SECTION

Colloidal Oatmeal 12% Skin Protectant

INACTIVE INGREDIENT SECTION

Almond Oil, Beeswax, Grapefruit, Jojoba Oil,

Lanolin, Peppermint, Vitamin E Oil

INDICATIONS & USAGE SECTION

Temporarily relieves itching from sunburn.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep Out Of Reach Of Children.
If swallowed get medical help or contact
a poison control center immediately.

DOSAGE & ADMINISTRATION SECTION

Apply to affected area
Rub in circular motion
Apply as needed

OTC - STOP USE SECTION

Condition worsens

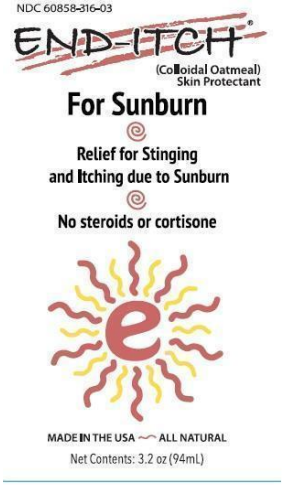
Sensitivity develops or increases

Symptoms last more than 7 days or

clear up and occur again in a few days

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

End Itch Sunburn.jpg



END-ITCH FOR SUNBURN

end-itch for sunburn cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60858-316
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
oatmeal (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	oatmeal	11.62 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GRAPEFRUIT (UNII: O82C39RR8C)	
JOJOBA OIL (UNII: 724GKU717M)	
LANOLIN (UNII: 7EV65EAW6H)	
PEPPERMINT (UNII: V95R5KMY2B)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60858-316-03	90.71 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/15/2015	

Labeler - Crystal Connections, LLC (016582119)

Establishment

Name	Address	ID/FEI	Business Operations
American Pharmaceutical and Cosmetics, Inc.		038023805	manufacture(60858-316)

Revised: 5/2015 Crystal Connections, LLC