

END-ITCH- oatmeal 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 external use only

Do not use on open cuts

When using this product do not get into eyes

Do not ingest

Stop use and ask a doctor if:

Condition worsens

Sensitivity develops or increases

Symptoms last more than 7 days or clear up and occur again in a few days

PURPOSE

Skin protectant

DOSAGE & ADMINISTRATION

Apply to affected area

Rub vigorously

Rinse off salt only

Pat dry the waxy residue

Apply as needed

ACTIVE INGREDIENT

Oatmeal

INACTIVE INGREDIENT

Almond oil

Beeswax

Jojoba oil

Lanolin

Lavender

Sea salt

Vitamin E Oil

OTC - KEEP OUT OF REACH OF CHILDREN

If swallowed get medical help or contact a poison control center immediately

INDICATIONS & USAGE

Temporarily protects and helps relieve minor skin irritation and itching due to: poison ivy, insect bites, eczema

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

end_itch.jpg



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



end_itch 1oz.jpg

END-ITCH

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60858-314
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.0287 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
Yellow Wax (UNII: 2ZA36H0S2V)	
JOJOBA OIL (UNII: 724GKU717M)	
LANOLIN (UNII: 7EV65EAW6H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60858-314-04	113.4 g in 1 BOTTLE		
2	NDC:60858-314-01	28.35 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/06/2014	

Labeler - Crystal Connections, LLC (016582119)**Establishment**

Name	Address	ID/FEI	Business Operations
American Pharmaceuticals and Cosmetics		038023805	manufacture(60858-314)