

YUMA- oatmeal soap
Yuma Outdoors 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.

Drug Facts

Active Ingredients

Colloidal Oatmeal (avena sativa) 1%

Purpose

Skin Protectant

Uses • temporarily protects and helps relieve minor skin irritation and itching due to •poison ivy, oak or sumac •insect bites •rashes

Warnings For external use only

When using this product •do not get into eyes •stop use and ask a doctor if •condition worsens

•symptoms last more than 7 days or clear up and occur again within a few days

•do not use on •deep or puncture wounds •animal bites

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

Directions •apply as needed

Inactive Ingredients Vegetable soap base (sodium palmate, sodium cocoate and/or sodium palm kemelate, water, glycerin, pentasodium pentetate), kaolin clay (kaolin), cocoa butter (theobroma cacao), sodium chloride, aloe vera leaf (aloe barbadensis), rosemary oil (rosmarinus officinalis), menthol (mentha arvensis), allantoin (ureidohydantoin), green tea (camelia sinensis), lemongrass (cymbopogon citratus), ammonium alum, eucalyptus oil (eucalyptus globulus), peppermint oil (mentha piperita), zinc ricinoleate, FD&C Yellow No. 10, FD&C Green No. 5.

Package Label - Principal Display Panel – Yuma Backwoods Survivor Carton



YUMA

oatmeal soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75933-1425
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1.205 g

Inactive Ingredients				
Ingredient Name				Strength
ALOE (UNII: V5VD430YW9)				
ROSEMARY (UNII: IJ67X351P9)				
MENTHA ARVENSIS FLOWER OIL (UNII: Q129Z1W6Y2)				
ALLANTOIN (UNII: 344S277G0Z)				
CAMELLIA SINENSIS ROOT (UNII: 8H54O0V2K3)				
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)				
POTASSIUM ALUM (UNII: 1L24V9R23S)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
ZINC RICINOLEATE (UNII: BOH1Z111J2)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)				
SODIUM COCOATE (UNII: R1TQH25F4I)				
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)				
KAOLIN (UNII: 24H4NWX5CO)				
COCOA BUTTER (UNII: 512OYT1CRR)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75933-1425-1	1 in 1 CARTON		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	06/01/2011		

Labeler - Yuma Outdoors LLC (965948461)

Establishment			
Name	Address	ID/FEI	Business Operations
Vanguard Soap LLC		831404954	MANUFACTURE