ECZEMA- oatmeal lotion/shampoo ORGANIC & SUSTAINABLE BEAUTY

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.

ECZEMA SHAMPOO & BODYWASH

Drug Facts

Active ingredient

Colloidal Oatmeal 1%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to:

- Rashes
- Eczema
- Poison ivy, oak, or sumac
- Insect bites

Warnings

External use only.

When using this product

- patch test before use
- keep out of eves
- clean with soap and water to remove
- to avoid slipping, use mat in tub or shower

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

Keep out of reach of children. If swallowed, get medical help or contact Poison Control within the U.S. (1-800-222-1222)

Directions

- dispense a dime-to-quarter sized amount into palm, massage into wet hair starting at the scalp and working to the ends. Rinse.
- for extra cleansing, allow to sit for 30 seconds and then rinse.

Other information

You may report a serious adverse reaction event from using this product to: 5933 Bowcroft St. Los Angeles, CA 90016

Inactive ingredients

Water, decyl glucoside, lauryl glucoside, quillaja saponaria bark extract, glycerine, allantoin, calendula officinalis flower extract, viola tricolor extract, yucca schidigera root extract, aloe barbadensis leaf juice, simmondsia chinensis (jojoba) seed oil, hydrolyzed quinoa, xanthan gum, panthenol, phytic acid, gluconolactone, sodium benzoate.

PRINCIPAL DISPLAY PANEL - 562 mL Bottle Label

CALIF♥RNIA BABY®

TRUSTED SINCE 1995

eczema therapy

SHAMPOO & BODYWASH SKIN PROTECTANT

GLUTEN FREE + STEROID FREE

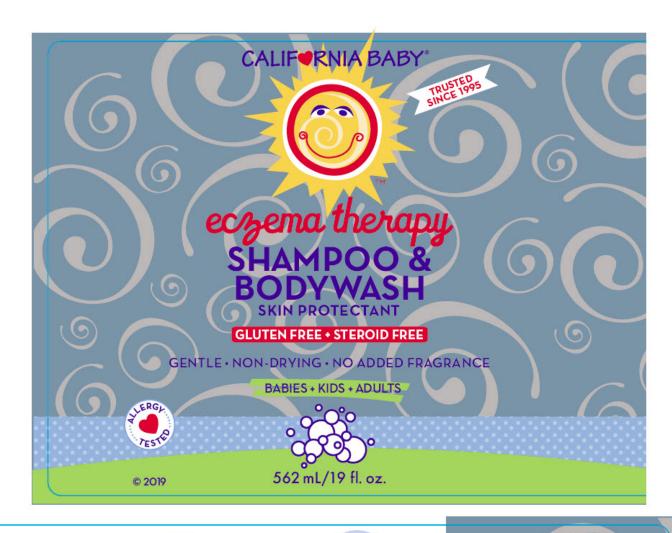
GENTLE • NON-DRYING • NO ADDED FRAGRANCE

BABIES + KIDS + ADULTS

ALLERGY TESTED

© 2019

562 mL/19 fl. oz.









NO SCENT-MASKING CHEMICALS

Drug Facts

Active ingredient:

Purpose

Colloidal Oatmeal 1%

...Skin Protectant

Uses: Temporarily protects and helps relieve minor skin irritation and itching due to: • Rashes • Eczema • Poison ivy, oak, or sumac • Insect bites

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

Keep out of reach of children. If swallowed, get medical help or contact Poison Control within the U.S. (1-800-222-1222)

Directions: Dispense a dime- to quarter-sized amount into palm, and massage into wet hair, starting at the scalp and working toward the ends. Rinse. For extra cleansing, allow to sit for 3O seconds and then rinse.

Other information: You may report a serious adverse reaction event from using this product to: 5933 Bowcroft St. Los Angeles, CA 90016.

Inactive ingredients: Water, calendula officinalis flower extract, decyl glucoside, lauryl glucoside, quillaja saponaria bark extract, glycerine, allantoin, viola tricolor extract, yucca schidigera root extract, aloe barbadensis leaf juice, simmondsia chinensis (jojoba) seed oil, hydrolyzed quinoa, xanthan gum, panthenol, phytic acid, gluconolactone, sodium benzoate.

CERTIFIED ORGANIC INGREDIENTS: COLLOIDAL OATMEAL, QUILLA JA SAPON ARIA BARK EXTRACT, CALENDULA, VIOLA TRICOLOR EXTRACT AND ALOE BARBADENSIS LEAF JUICE AND SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL. DECYL GULOOSIDE, LAURYL GLUCOSIDE, AND GLYCERINE ARE SOURCED FROM SUSTAINBALE RALLER FRUIT KERNEL AND/OR COCONUT. GLUCONOLACTONE IS SOURCED FROM CORN (NON-GMO).

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UPC/FPO 7 92692 00115 0

ECZEMA

oatmeal lotion/shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52915-010
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	10 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
decyl glucoside (UNII: Z17H97EA6Y)		
lauryl glucoside (UNII: 76LN7P7UCU)		
quillaja saponaria bark (UNII: 8N0K3807ZW)		
glycerin (UNII: PDC6A3C0OX)		
allantoin (UNII: 344S277G0Z)		
calendula officinalis flower (UNII: P0M7O4Y7YD)		
VIOLA TRICOLOR WHOLE (UNII: 9Q24RAI43V)		
yucca schidigera root (UNII: E2H9ET15AT)		
aloe vera leaf (UNII: ZY81Z83H0X)		
jojoba oil (UNII: 724GKU717M)		
quinoa oil (UNII: M437LS0K52)		
xanthan gum (UNII: TTV12P4NEE)		
panthenol (UNII: WV9CM0O67Z)		
fytic acid (UNII: 7IGF0S7R8I)		
gluconolactone (UNII: WQ29KQ9POT)		
sodium benzoate (UNII: OJ245FE5EU)		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52915-010- 19	562 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2012	
2	NDC:52915-010- 05	14 mL in 1 TUBE; Type 0: Not a Combination Product	10/01/2012	
3	NDC:52915-010- 85	251 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2012	

Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC MONOGRAPH FINAL	part347	10 / 0 1 / 20 12	

Labeler - ORGANIC & SUSTAINABLE BEAUTY (020085717)

Revised: 11/2020 ORGANIC & SUSTAINABLE BEAUTY