

STUDIO35 ECZEMA- colloidal oatmeal cream

Walgreen Company

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.

studio35™ Eczema Cream

Active ingredient

Colloidal Oatmeal 1%

Purpose

Skin Protectant

Uses

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

- Eczema
- Rashes

Warnings

For external use only.

When using this product

- do not get into eyes.

Stop use and ask a doctor if

- conditions 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 a Poison Control Center right away.

Directions

- Apply as needed

Inactive ingredients

water, glycerin, distearyldimonium chloride, isopropyl palmitate, cetearyl alcohol, petrolatum, dimethicone, steareth-21, panthenol (pro-vitamin B5), benzalkonium chloride, ceramide 3, ceramide 6-ii, ceramide 1, phytosphingosine, cholesterol, sodium lauroyl lactylate, carbomer, xanthan gum, avena sativa (oat) kernel oil, avena sativa (oat) kernel extract, sodium chloride, avena sativa (oat) kernel flour,

triethanolamine.

Questions or comments?

Call 1-800-925-4733.

Package/Label Principal Display Panel

studio35™

COMPARE TO
AVEENO® ACTIVE
NATURALS® ECZEMA
THERAPY MOISTURIZING CREAM*

**SKIN PROTECTANT
ECZEMA
CREAM**

WITH NATURAL
COLLOIDAL
OATMEAL

HELPS TO RELIEVE
DRY, ITCHY SKIN
DUE TO ECZEMA

STEROID-FREE &
FRAGRANCE-FREE

DERMATOLOGIST TESTED

NET WT 7.3 OZ (207 g)

Enriched with soothing oatmeal, this innovative cream offers relief to help care for dry, itchy skin, while intensely moisturizing it. It helps to fortify the skin's natural barrier functions while helping to prevent the recurrence of dry skin. The formula is enriched with ceramides, essential lipids naturally found in the skin, to enhance and restore the skin's natural protective function.

*This product is not manufactured or distributed by Johnson & Johnson®, owner of the registered trademark Aveeno® Active Naturals®.

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MADE IN ISRAEL

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Drug Facts

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MADE IN ISRAEL



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SKIN PROTECTANT
**ECZEMA
CREAM**

WITH NATURAL
COLLOIDAL
OATMEAL
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DUE TO ECZEMA
STEROID-FREE &
FRAGRANCE-FREE
DERMATOLOGIST TESTED



NET WT 7.3 OZ (207 g)

Carton Label

STUDIO35 ECZEMA			
colloidal oatmeal cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4246

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARETH-21 (UNII: 53J3F32P58)	
PANTHENOL (UNII: WV9CM0O67Z)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
OAT (UNII: Z6J799EAJK)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4246-11	207 g in 1 TUBE; 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	09/01/2014	

Labeler - Walgreen Company (008965063)