ECODERM - colloidal oatmeal lotion Phillips 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.

DRUG FACTS

DRUG FACTS

Drug Facts

Active Ingredient Purpose

Colloidal Oatmeal (0.1%) Skin Protectant Aka Avena sativa (0.1%) Skin Protectant

Uses

n Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

Warnings

n For external use only

n Keep away from children

n Avoid contact with eyes

n May be harmful if swallowed or inhaled

Ask a physician

n If symptoms last for more than 7 days or clear up and recur within a few days.

n If the conditions do not improve.

n Before use on children under 2 years.

n Before use if you are allergic to any ingredients listed on this label.

Directions

Apply to affected skin area and rub gently. Repeat the process as needed.

Other information

This is an OTC skin protectant drug product for human use. Store at 40 to 100 degrees F. Net contents: 3 mL (dropper bottle). This product contains no alcohol; no animal products.

Inactive ingredients

Water, dimethyl sulfoxide, dipropylene glycol, ascorbic acid, sorbic acid, magnesium stearate, stearic acid.

Questions and Side effects

Use of this product results in no known side effects when used according to directions. Phillips Company, 311 Chickasaw Street, Millerton, OK USA 74750; Tel. 580-746-2430 Email address: hp@valliant.net

ACTIVE INGREDIENTS

Colloidal Oatmeal (0.1%) Skin Protectant Aka Avena sativa (0.1%) Skin Protectant

ASK DOCTOR

Ask a doctor

n If symptoms last for more than 7 days or clear up and recur within a few days.

n If the conditions do not improve.

n Before use on children under 2 years.

n Before use if you are allergic to any ingredients listed on this label.

DO NOT USE

n Avoid contact with eyes n May be harmful if swallowed or inhaled

CHILDREN

Keep away from children Avoid contact with eyes May be harmful if swallowed or inhaled

PURPOSE

n Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

STOP USE

n For external use only

n Keep away from children

n Avoid contact with eyes

n May be harmful if swallowed or inhaled

Ask a physician

n If symptoms last for more than 7 days or clear up and recur within a few days.

n If the conditions do not improve.

n Before use on children under 2 years.

n Before use if you are allergic to any ingredients listed on this label.

WHEN USING

Apply to affected skin area and rub gently. Repeat the process as needed. Store at 40 to 100 degrees F.

n Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

n For external use only

n Keep away from children

n Avoid contact with eyes

n May be harmful if swallowed or inhaled

Ask a physician If symptoms last for more than 7 days or clear up and recur within a few days.

WARNINGS

n For external use only n Keep away from children

n Avoid contact with eyes n May be harmful if swallowed or inhaled

DOSAGE & ADMINISTRATION

Apply to affected skin area and rub gently. Repeat the process as needed.

USE

Uses

n Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

Directions

Apply to affected skin area and rub gently. Repeat the process as needed.

INACTIVE INGREDIENTS

Inactive ingredients

Water, dimethyl sulfoxide, dipropylene glycol, ascorbic acid, sorbic acid, magnesium stearate, stearic acid.

Image of product



ECODERM

colloidal oatmeal lotion

Pro	duct	Infor	mation
FIU		HIIIUI	IIIauwii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:43074-113

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)	OATMEAL	0.001 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
dimethyl sulfoxide (UNII: YOW8V9698H)	
ascorbic acid (UNII: PQ6CK8PD0R)	
dipropylene glycol (UNII: E107L85C40)	
water (UNII: 059QF0KO0R)	
sorbic acid (UNII: X045WJ989B)	
magnesium stearate (UNII: 70097M6I30)	
stearic acid (UNII: 4ELV7Z65AP)	
sodium dodecylbenzenesulfonate (UNII: 554127163Y)	

Packaging

1	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43074-113-24	1 in 1 BOX		
1	NDC:43074-113-23	3 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/30/2010	

Labeler - Phillips Company (612368238)

Establishment				
Name	Address	ID/FEI	Business Operations	
Phillips Company		612368238	manufacture	

Revised: 1/2011 Phillips Company