

CVS SOOTHING ITCH RELIEF - menthol lotion

CVS Pharmacy

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 ingredient

Purpose

Menthol 0.1%.....External analgesic lotion

Uses for the treatment of itching associated with minor skin irritations.

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

Uses for the treatment of itching associated with minor skin irritations.

Warnings

For external use only

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens - irritation occurs
- symptoms persist for 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. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Directions

Adults and children 2 years of age and older,

- apply to affected area not more than 3 to 4 times daily

Children under 2 years of age,

- consult a doctor

Inactive Ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, benzyl alcohol, caprylic/capric triglyceride, cetearyl alcohol, cetyl alcohol, colloidal oatmeal, dimethicone, DMDM hydrantoin, glycerin, glyceryl stearate SE, isopropyl isostearate, myristyl, myristate, octyldodecanol,

oenothera biennis oil (evening primrose), PEG-40 castor oil, phenoxyethanol, polyglyceryl-3 methylglucose distearate, potassium sorbate, purified water, sodium citrate



dry skin therapy



Soothing itch-relief

Fast itch-relief

Cool menthol with natural oatmeal

Non-irritating

Unscented

*Compare to Eucerin®
Calming Itch-relief**


EXTERNAL ANALGESIC LOTION

6.8 fl oz (200 mL)

L070CVS6.8OZ-2


Drug Facts	
Active ingredient	Purpose
Menthol 0.1%	External analgesic lotion
Uses for the temporary relief of itching associated with minor skin irritations.	
Warnings	
For external use only	
When using this product avoid contact with the eyes	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • condition worsens • irritation occurs • symptoms persist for 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	
Adults and children 2 years of age and older, <ul style="list-style-type: none"> • apply to affected area not more than 3 to 4 times daily Children under 2 years of age, <ul style="list-style-type: none"> • consult a doctor 	
Inactive ingredients	
acrylates/C10-30 alkyl acrylate crosspolymer, benzyl alcohol, caprylic/capric triglyceride, cetearyl alcohol, cetyl alcohol, colloidal oatmeal, dimethicone, DMDM hydantoin, glycerin, glyceryl stearate SE, isopropyl isostearate, myristyl myristate, octyldodecanol, oenothera biennis oil (evening primrose), PEG-40 castor oil, phenoxyethanol, polyglyceryl-3 methylglucose distearate, potassium sorbate, purified water, sodium citrate	

*This product is not manufactured or distributed by Beiersdorf AG, owner of the registered trademark Eucerin®.



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R070CVS6.8OZ-2

CVS SOOTHING ITCH RELIEF			
menthol lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-051
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER 1342 (UNII: 809Y72KV36)	
GLYCERIN (UNII: PDC6A3C0OX)	
OATMEAL (UNII: 8PI54V663Y)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
ISOPROPYL STEARATE (UNII: 43253ZW1MZ)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-051-37	200 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture