999 ITCH RELIEF- menthol ointment
China Resources Sanjiu Medical & Pharmaceutical Co Ltd

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.

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999 ITCH RELIEF OINTMENT

ACTIVE INGREDIENTS

Menthol 1%

Camphor (synthetic) 1%

Dexamethasone Acetate 0.075%

Purpose

External Analgesic

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Anti-allergic

For the temporary relief of pain caused by itching and rashes, poison ivy, poison oak

Warnings

For external use only. Avoid contact with the eyes. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and seek medical advice if

Condition worses. Symptoms persisit for more than 7 days. Symptoms clear up and occur again within a few days. Excessive irritation of the skin develops.

Directions

Pregnant and children under 2 years of age. Do not use, consult a doctor.

Warnings

Keep out of reach of children.

Directions

Adult and children 2 years of age and older. Apply liberally to affected area not more than 5 times daily and 5-8 times per day for some severe cases or follow doctor's instruction.

Other Information

Keep in a lightly closed container. Store at 8 to 30 degree centigrade (46-86 Fahrenheit) in a dry plac away from sunlight.

Inactive Ingredients

Hexadecanolactone

Ethylparaben

Glycerin

Glycertyl Monostearate

Drug Facts

文件名	CP2013-10-0611 皮炎平软膏纸盒（美国麦斯特201301版）彩样5.ai					九星印刷
颜 色	C M Y K 专银		尺 寸	39*23*135mm	条码等级	
制作人	谢顺秀	日期	10-17	文件路径	\\serverctp\制作区\YXH苑晓辉\2013年7月\CP2013-07-0900\out	
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999 ITCH RELIEF

menthol ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12753-930
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	200 mg in 20000 mg
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	200 mg in 20000 mg
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	15 mg in 20000 mg

Inactive Ingredients

Ingredient Name	Strength
HEXADECANOLACTONE (UNII: 64E2HO00C7)	
Ethylparaben (UNII: 14255EXE39)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12753-930-19	20000 mg in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/03/2003	

Labeler - China Resources Sanjiu Medical & Pharmaceutical Co Ltd (544695711)

Registrant - China Resources Sanjiu Medical & Pharmaceutical Co Ltd (544695711)

Establishment

Name	Address	ID/FEI	Business Operations
China Resources Sanjiu Medical & Pharmaceutical Co Ltd		544695711	manufacture(12753-930)

Revised: 10/2013 China Resources Sanjiu Medical & Pharmaceutical Co Ltd