AMERICAN SAFETY AND FIRST AID- hydrocortisone acetate cream Orazen Inc

71927-015 American Safety & First Aid Hydrocortisone Cream 1%

Drug Facts

Active Ingredient

Hydrocortisone Acetate 1%

Purpose

Anti-Itch Cream

Uses

- for the temporary relief of itching associated with minor irritations and rashes
- Other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

for the treatment of diaper rash. Consult a doctor. Complete Warnings See Card or Box

Keep out of reach of children.

If swallowed contact a Poison Control Center right away.

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: do not use

Inactive Ingredients

Cetearyl alcohol, Ceteareth-20, Ethylhexyglycerin, Phenoxyethanol, Glycerin, Glycerol fatty acid ester, Mineral Oil, Petrolatum, Water

Package Labeling:



Hydrocortisone Cream 1%

Maximum Strength Anti-Itch

Drug Facts

Active ingredients Purpose

Hydrocortisone Anti-itch Acetate 1%cream

Uses ■ for the temporary relief of itching associated with minor irritations and rashes ■ other uses of this product should be only under the advice and supervision of a doctor

|*Warnings* |For external use only

NET WT 0.9g (1/32 OZ)

Drug Facts (continued)

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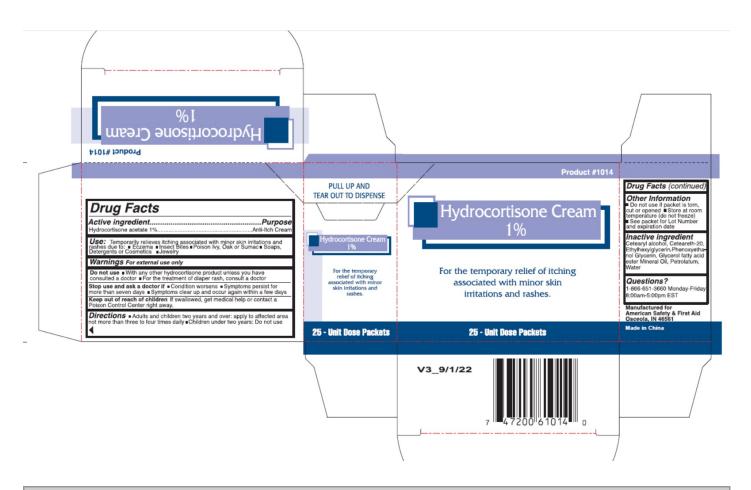
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Mfg. for American Safety & First Aid Osceola, IN 46561

Made in China



AMERICAN SAFETY AND FIRST AID

hydrocortisone acetate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71927-015

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE -

HYDROCORTISONE 10 mg **ACETATE**

UNII:W4X0X7BPJ) in 1 g

Inactive Ingredients

Ingredient Name Strength PETROLATUM (UNII: 4T6H12BN9U)

POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

GLYCERYL 1-STEARATE (UNII: 258491E1RZ)

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

GLYCERIN (UNII: PDC6A3C0OX)

MINERAL OIL (UNII: T5L8T28FGP)

WATER (UNII: 059QF0KO0R)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71927-015- 02	25 in 1 BOX	10/17/2022			
1	NDC:71927-015- 01	0.9 g in 1 POUCH; Type 0: Not a Combination Product				

Marketing In	arketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	10/17/2022			

Labeler - Orazen Inc (080916640)

Revised: 1/2024 Orazen Inc