ROOSIN- hydrocortisone acetate cream
ROOSIN MEDICAL 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.

81552-003 Hydrocortisone Cream

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Use

Temporary relieves itching associated with minor irritations and rashes

Other uses should be only under the advice and supervision of a doctor

WARNINGS

For external use only

Do not use
- In or near eyes
- For diaper rash, consult a doctor

When using this product
- Do not use any other hydrocortisone products unless you have contacted a doctor

Stop use and ask a doctor if

Condition worsens or persists for more than 7 days

Symptoms clear up and occur within a few days

Keep out of reach of children. If ingested, get medical help or contact a poison control center right away

Directions

Adults and children two years of age and older: Apply to affected area not more than 3-4 timesdaily

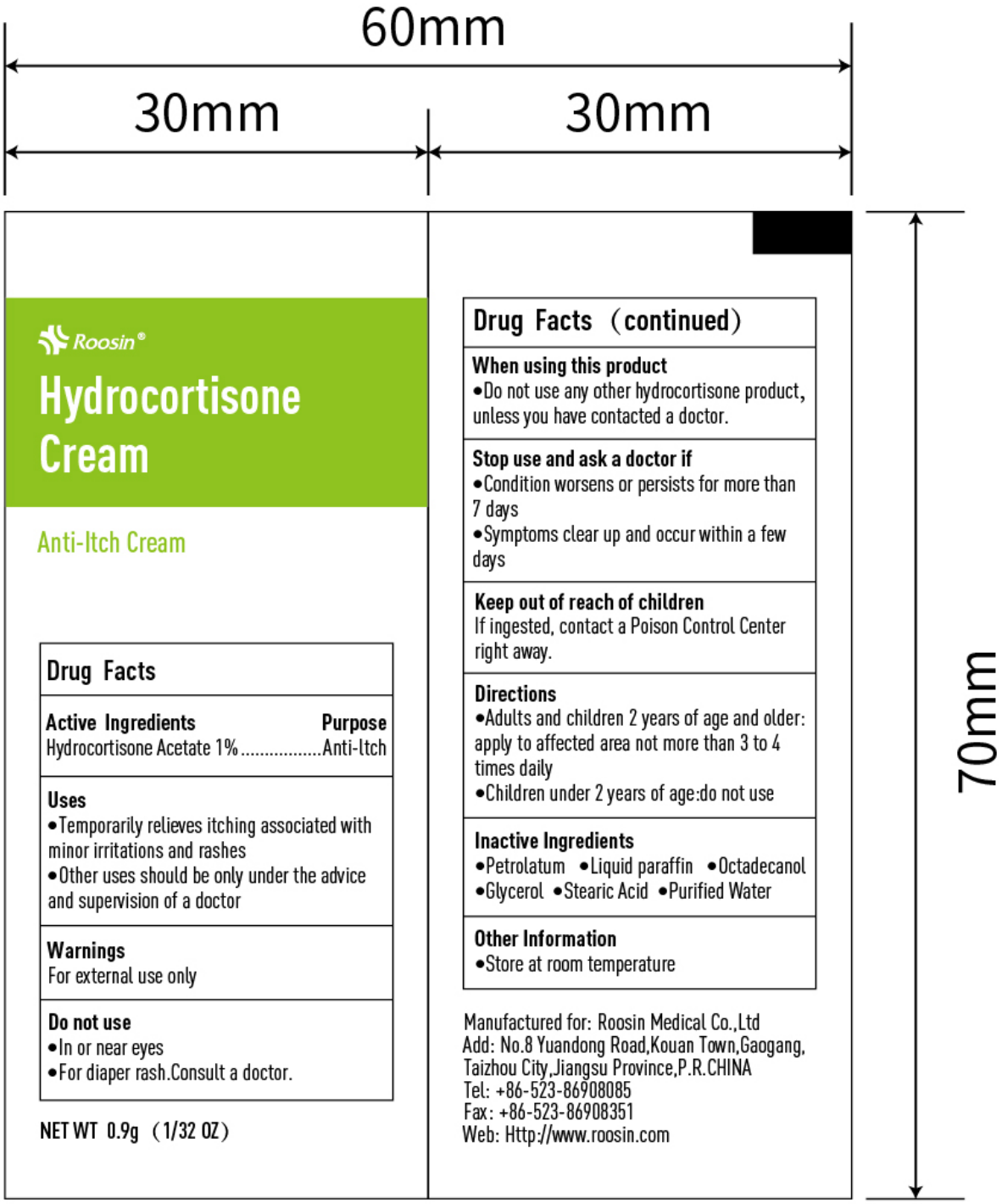
Children under 2 years of age: Do not use

Inactive ingredients

Petrolactum, Liquid Paraffin, Octadecanol, Glycerol, Stearic Acid, Purified Water

Other Information

Store at room temperature



ROOSIN

hydrocortisone acetate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81552-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
OCTADECANOL (MIXTURE OF ISOMERS) (UNII: C6BPY2QY39)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCEROL FORMAL (UNII: 3L7GR2604E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81552-003-01	0.9 g in 1 TUBE; Type 0: Not a Combination Product	04/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/20/2021	

Labeler - ROOSIN MEDICAL CO., LTD (527587815)

Establishment

Name	Address	ID/FEI	Business Operations
ROOSIN MEDICAL CO., LTD		527587815	manufacture(81552-003)

Revised: 12/2021 ROOSIN MEDICAL CO., LTD