ROOSIN NEOMYCIN ANTIBIOTIC- neomycin sulfate ointment
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.

81552-001 Neomycin

Active Ingredient

Neomycin Sulfate 0.556%

Purpose

First Aid Antibiotic

Use

First aid to help prevent infection in minor cuts scrapes burns

WARNINGS

For external use only

Do not use
- In eyes
- Over large areas of the body
- For more than one week unless directed by a doctor
- If you are allergic to any of the ingredients

Ask doctor before use if you have puncture wounds, animal bites, or serious burns

Stop use an ask a doctor if
- A rash or allergic reaction develops
- Condition worsens or persists

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

Directions

Clean affected area

Apply a small amount 1-3 times daily

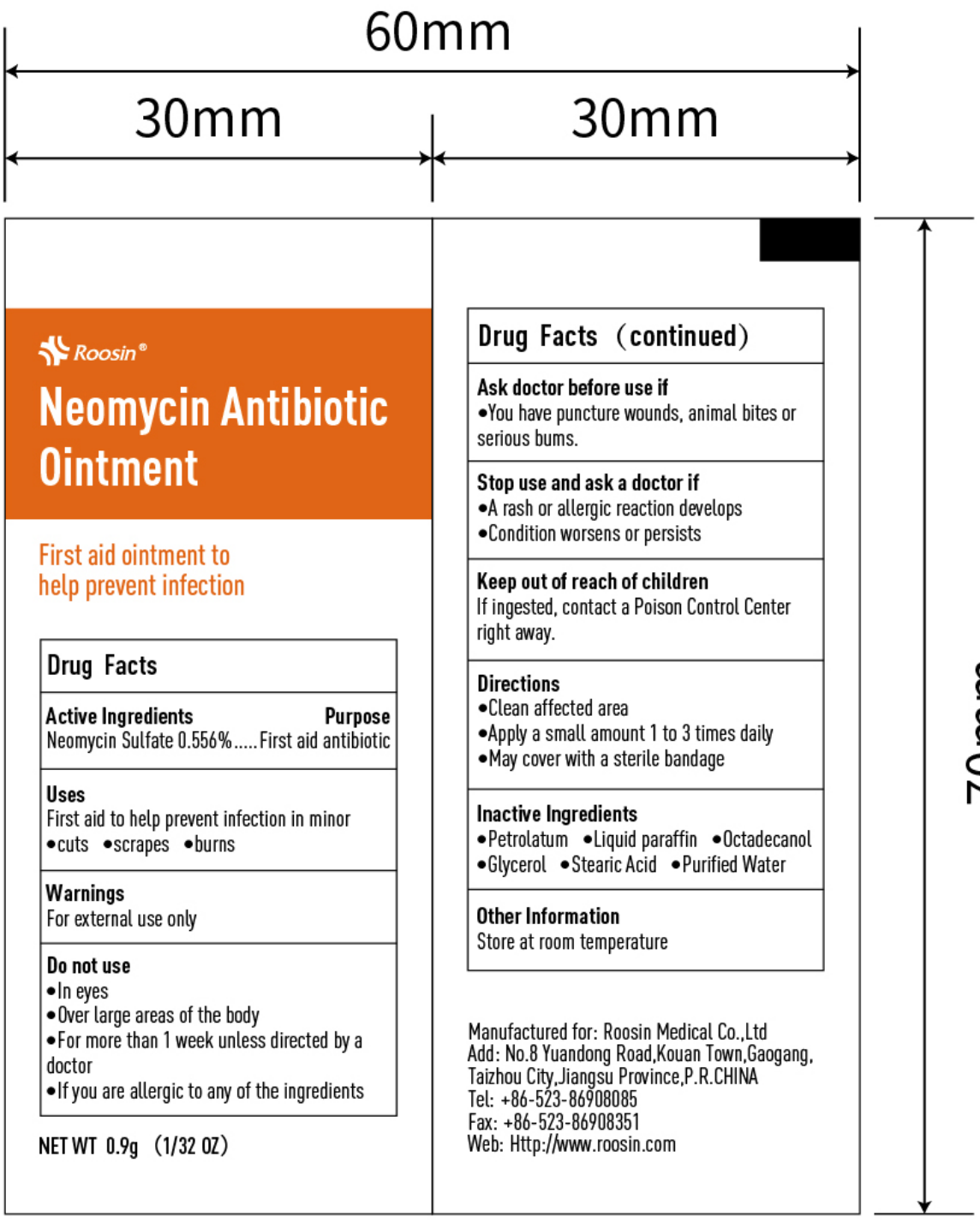
May cover with a sterile bandage

Other information

Store at room temperatuure

Inactive ingredients

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



ROOSIN NEOMYCIN ANTIBIOTIC

neomycin sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81552-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	0.556 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:81552-001-01	0.9 g in 1 TUBE; Type 0: Not a Combination Product	04/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/12/2021	

Labeler - ROOSIN MEDICAL CO., LTD (527587815)

Establishment

Name	Address	ID/FEI	Business Operations
ROOSIN MEDICAL CO., LTD		527587815	manufacture(81552-001)

Revised: 12/2021 ROOSIN MEDICAL CO., LTD