ROOSIN TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b 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.

81552-004 Triple Antibiotic Ointment

Active Ingredient

Bacitracin Zinc 0.048%

Neomycin Sulfate 1%

Polymyxin B Sulfate 0.6%

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Use

First aid to help prevent infection in minor cuts scrapes burns

WARNINGS

For external use only

Do not use

- In the eyes
- Over large areas of the body
- If you are allergic to any of the ingredients
- Longer than 1 week unless directed by a doctor

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

Directions

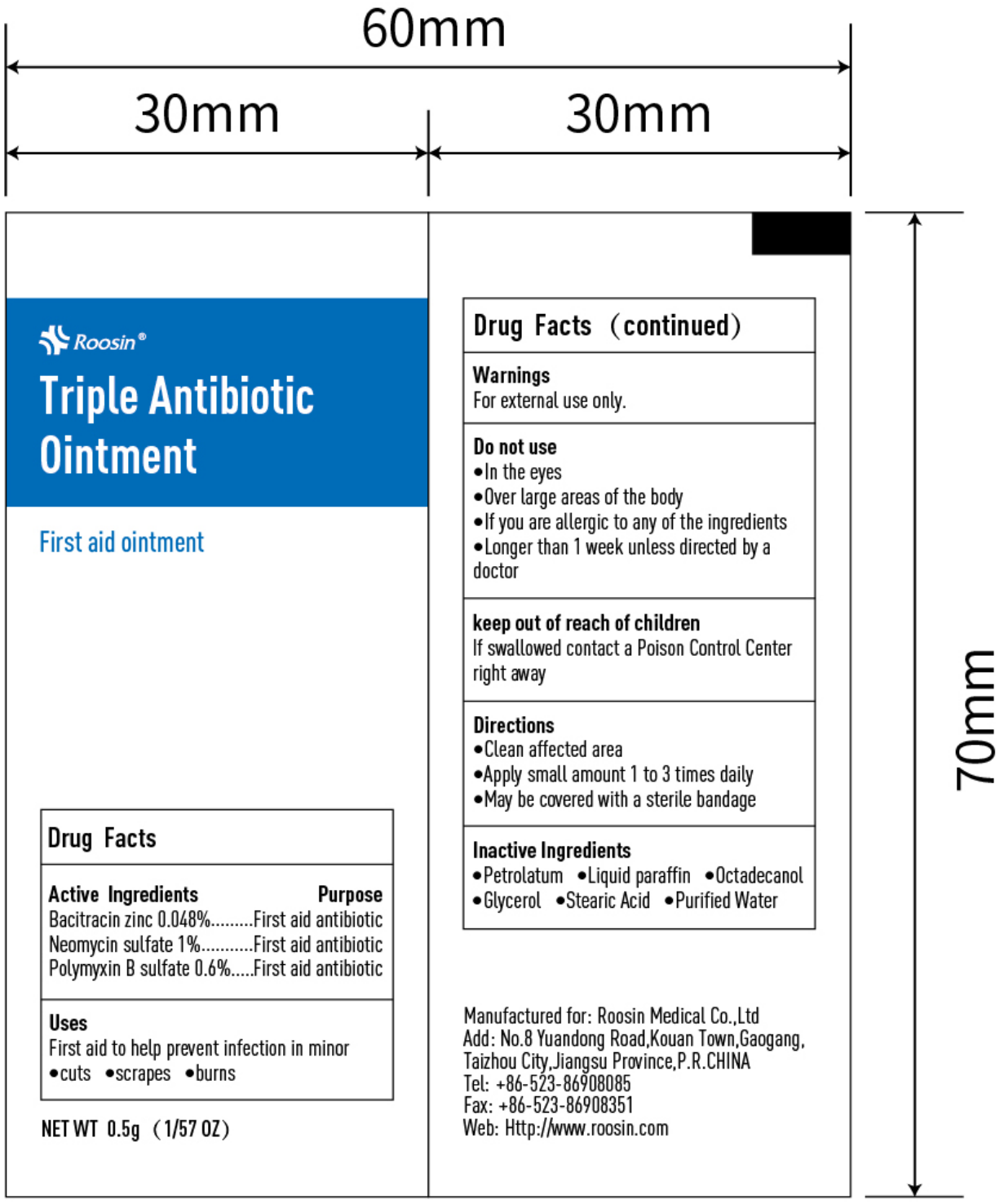
Clean affected area

Apply small amount 1 to 3 times daily

May be covered with a sterile bandage

Inactive ingredients

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



ROOSIN TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81552-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	0.048 g in 100 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	1 g in 100 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	0.6 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:81552-005-01	0.5 g in 1 TUBE; Type 0: Not a Combination Product	04/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/24/2021	

Labeler - ROOSIN MEDICAL CO., LTD (527587815)

Establishment

Name	Address	ID/FEI	Business Operations
ROOSIN MEDICAL CO., LTD		527587815	manufacture(81552-005)

Revised: 4/2021 ROOSIN MEDICAL CO., LTD