SINGLE ANTIBIOTIC WITH NEOMYCIN- neomycin sulfate ointment Safetec of America

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.

Drug Facts

Active Ingredient (in each gram)

Neomycin Sulfate (3.5 mg Neomycin)

Purpose

First Aid Antibiotic

Uses:

First aid to help prevent infection in minor cuts, scrapes, and burns.

Warnings:

For external use only.

Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center directly.

Do Not Use:

- in the eyes or over large areas of the body, or on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor
- if allergic to any of the ingredients

Stop use, ask a doctor if:

- condition persists or gets worse
- a rash or allergic reaction develops

Directions:

- clean affected area
- apply a small amount of this product (equal to the surface area of the tip of finger) 1 to 3 times daily
- may cover with a sterile bandage

Inactive ingredients:

mineral oil, petrolatum

Questions or Comments? 1-800-456-7077

Principal Display Panel - Box Label

NDC 61010-6700-2

Safetec

First Aid

Single Antibiotic Ointment

- with Neomycin
- First Aid to Help Prevent Infection In Minor Cuts, Scrapes, and Burns

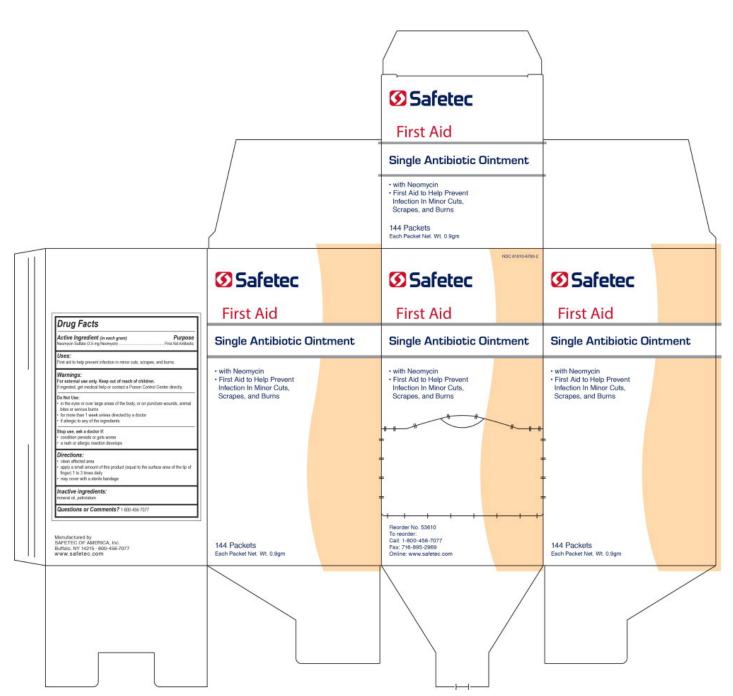
Reorder No. 53610

To reorder:

Call: 1-800-456-7077

Fax: 716-895-2969

Online: www.safetec.com



Principal Display Panel - Pouch Label

Safetec

Single Antibiotic Ointment

(Neomycin)

0.9 g (1/32 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077

Safetec Single Antibiotic Ointment

(Neomycin)

0.9 g (1/32 oz.)

Safetec of America, Inc. Buffalo, NY 14215 800-456-7077

Drug Facts

Active ingredient Purpose (in each gram) Neomycin Sulfate First Aid

Neomycin Sulfate First Aid (3.5 mg Neomycin). . . Antibiotic

Use first aid to help prevent infection in minor scrapes, cuts, and burns

Warnings
For external use only

Principal Display Panel - Box Label

NDC 61010-6700-3

Safetec

First Aid

Drug Facts (continued)

Warnings (continued)

Do not use ■ in eyes ■ over large areas of the body or on puncture wounds, animal bites or serious burns ■ for more than 1 week unless directed by a doctor ■ if you are allergic to any of the ingredients

Stop use and ask a doctor if

■ a rash or allergic reaction develops ■ condition worsens or persists

Keep out of reach of children If ingested, contact a Poison Control Center right away.

Directions ■ clean affected area ■ apply a small amount 1 to 3 times daily ■ may cover with a sterile bandage

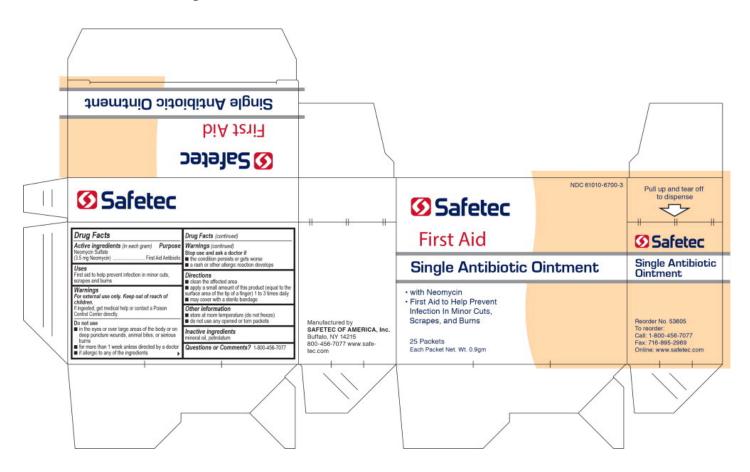
Inactive ingredients mineral oil, petrolatum

Single Antibiotic Ointment

- with Neomycin
- First Aid to Help Prevent Infection In Minor Cuts, Scrapes, and Burns

25 Packets

Each Packet Net. Wt. 0.9gm



Principal Display Panel - Pouch Label

Safetec

Single Antibiotic Ointment

(Neomycin)

0.9 g (1/32 oz.)

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Buffalo, NY 14215

800-456-7077

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0.9 g (1/32 oz.)

Safetec of America, Inc. Buffalo, NY 14215 800-456-7077

Drug Facts

Purpose Active ingredient (in each gram) Neomycin Sulfate (3.5 mg Neomycin). . . Antibiotic

Use first aid to help prevent infection in minor scrapes, cuts, and burns

Warnings For external use only

Drug Facts (continued)

Warnings (continued)

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Directions ■ clean affected area ■ apply a small amount 1 to 3 times daily ■ may cover with a sterile bandage

Inactive ingredients mineral oil, petrolatum

SINGLE ANTIBIOTIC WITH NEOMYCIN

neomycin sulfate ointment

Product Information

NDC:61010-6700 Product Type HUMAN OTC DRUG Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength 3.5 mg in 1 g

neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:I16QD7X297) neomycin

Inactive Ingredients

Ingredient Name Strength

petrolatum (UNII: 4T6H12BN9U)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:61010-6700-2	144 in 1 BOX	11/13/2008				
1	NDC:61010-6700-1	0.9 g in 1 POUCH; Type 0: Not a Combination Product					
2	NDC:61010-6700-3	25 in 1 BOX	11/13/2008				
2	NDC:61010-6700-1	0.9 g in 1 POUCH; Type 0: Not a Combination Product					

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph final	part333B	11/13/2008						

Labeler - Safetec of America (874965262)

Establishment								
Name	Address	ID/FEI	Business Operations					
Safetec of America, Inc.		874965262	MANUFACTURE(61010-6700)					

Revised: 12/2019 Safetec of America