VITACILINA NEOMYCIN SULFATE FIRST AID ANTIBIOTIC- neomycin sulfate ointment

Compania Internacional de Comercio, S.A.P.I de C.V.

VITACILINA NEOMYCIN SULFATE OINTMENT FIRST AID ANTIBIOTIC

Drug Facts

Active ingredient (in each gram)

Neomycin sulfate 5 mg (neomycin 3.5 mg)

Purpose

First aid antibiotic

Uses

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

Ask a doctor before use if you have

• deep or puncture wounds • animal bites • serious burns

Stop use and ask a doctor if

• the condition persists or gets worse • a rash or other allergic reaction develops

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Clean the affected area • Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily • May be covered with a sterile bandage

Other information

store at room temperature

Inactive ingredients

lanolin, methylparaben, petrolatum, propylparaben, vitamin A palmitate

Package Labeling: (54312-019-35)





Package Labeling: (54312-019-14)

NEOMYCIN SULFATE OINTMENT

FIRST AID ANTIBIOTIC

NET WT 1 OZ (28 g)

THIS UNIT NOT LABELED FOR RETAIL SALE. THIS UNIT IS PACKAGED IN AN OUTER CONTAINER. PLEASE SEE OUTER CONTAINER FOR COMPLETE DRUG FACTS INFORMATION.

ACTIVE INGREDIENT: NEOMYCIN 3.5 mg PURPOSE: FIRST AID ANTIBIOTIC USE: FIRST AID TO HELP PREVENT INFECTION IN MINOR CUTS, SCRAPES, AND 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. ASK A DOCTOR BEFORE USE IF YOU HAVE: DEEP OR PUNCTURE WOUNDS; ANIMAL BITES; SERIOUS BURNS. STOP USE AND ASK A DOCTOR IF: THE CONDITION PERSISTS OR GETS WORSE, A RASH OR OTHER ALLERGIC REACTION DEVELOPS.
KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL
CENTER RIGHT AWAY.

INACTIVE INGREDIENTS: LANOLIN, METHYLPARABEN, PETROLATUM, PROPYLPARABEN, VITAMIN A PALMITATE. DISTRIBUTED BY VITACILINA CORPORATION OF AMERICA, MCALLEN, TX 78501 MADE IN MEXICO. TO REPORT A SERIOUS ADVERSE EVENT CONTACT (956)631-6140

Lot, No. Expiration. Date.

30103-V2

Drug Facts

Active ingredient (in each gram) Neomycin sulfate 5 mg (neomycin 3.5 mg)

Purpose First aid antibiotic

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



NEOMYCIN SULFATE OINTMENT

FIRST AID ANTIBIOTIC

NET WT 1 OZ (28 g)

Drug Facts (continued)

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if the condition persists or gets worse a rash or other altergic reaction develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
■ Clean the affected area

■ apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily

MANIFACTURED BY
FARIMAGNO 3.4 de CY.
CALLE 2 NO. 42 PAROUR
FOUNTERIAL BENTO JUAREZ,
ASANTIAGO DE CUBERTARO,
CRO. C.P. 76121. MEDICO
DO SISTRIBUTED BY VITACILINA
CORPORATION OF AIRERICA,
MAGLE IN TARSON
MAGE IN MEDICO
TO REPORT A SERIOUS
ADVENSE EVISIT CONTACT.

Inactive ingredients lanolin, methylparaben, petrolatum, propylparaben, vitamin A palmitati

NEOMYCIN SULFATE OINTMENT

FIRST AID ANTIBIOTIC

NET WT 1 OZ (28 g)



Package Labeling:

NEOMYCIN SULFATE OINTMENT

FIRST AID ANTIBIOTIC

VITACILINA®

NET WT 1 OZ (28 g)

THIS UNIT NOT LABELED FOR RETAIL SALE. THIS UNIT IS PACKAGED IN AN OUTER CONTAINER. PLEASE SEE OUTER CONTAINER FOR COMPLETE DRUG FACTS INFORMATION.

ACTIVE INGREDIENT: NEOMYCIN SULFATE 5 mg (NEOMYCIN 3.5 mg) PURPOSE: FIRST AID ANTIBIOTIC USE: FIRST AID TO HELP PREVENT INFECTION IN MINOR CUTS, SCRAPES, AND 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. ASK A DOCTOR BEFORE USE IF YOU HAVE: DEEP OR PUNCTURE WOUNDS; ANIMAL BITES; SERIOUS BURNS. STOP USE AND ASK A DOCTOR IF: THE CONDITION PERSIST OR GETS WORSE; A RASH OR OTHER ALLERGIC

REACTION DEVELOPS. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

INACTIVE INGREDIENTS: LANGLIN METHYL PARABEN PETROLATI IM PROPYL PARABEN VITAMIN A

INACTIVE INGREDIENTS: LANOLIN, METHYLPARABEN, PETROLATUM, PROPYLPARABEN, VITAMIN A PALMITATE.

DISTRIBUTED BY TAISHO PHARMACEUTICAL CALIFORNIA, INC. MADE IN MEXICO.

TO REPORT A SERIOUS ADVERSE EVENT CONTACT 3528 TORRANCE BLVD. SUITE #320 TORRANCE, CA 90503





Package Labeling:



30104 -V5

NET WT 1 OZ (28 g)

NEOMYCIN SULFATE OINTMENT FIRST AID ANTIBIOTIC (R) **NET WT 1 OZ (28 g)** THIS UNIT NOT LABELED FOR RETAIL SALE. THIS UNIT IS PACKAGED IN AN OUTER CONTAINER, PLEASE SEE OUTER CONTAINER FOR COMPLETE DRUG FACTS INFORMATION. ACTIVE INGREDIENT: NEOMYCIN SULFATE 5 mg (NEOMYCIN 3.5 mg) PURPOSE: FIRST AID ANTIBIOTIC USE: FIRST AID TO HELP PREVENT INFECTION IN MINOR CUTS, SCRAPES, AND 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. ASK A DOCTOR BEFORE USE IF YOU HAVE: DEEP OR PUNCTURE WOUNDS; ANIMAL BITES; SERIOUS BURNS. STOP USE AND ASK A DOCTOR IF: THE CONDITION PERSIST OR GETS WORSE; A RASH OR OTHER ALLERGIC REACTION DEVELOPS. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY. INACTIVE INGREDIENTS: LANOLIN, METHYLPARABEN, PETROLATUM, PROPYLPARABEN, VITAMIN A PALMITATE. Lot, No. Expiration Date DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A. MADE IN MÉXICO

VITACILINA NEOMYCIN SULFATE FIRST AID ANTIBIOTIC

neomycin sulfate ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54312-019

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı			
ı	Ingredient Name	Basis of Strength	Strength
ı	NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g

Inactive Ingredients Ingredient Name Strength LANOLIN (UNII: 7EV65EAW6H) METHYLPARABEN (UNII: A2I8C7HI9T) PETROLATUM (UNII: 4T6H12BN9U) PROPYLPARABEN (UNII: Z8IX2SC10H) VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:54312-019- 35	1 in 1 CARTON	07/30/2016			
1		14 g in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:54312-019- 31	1 in 1 CARTON	07/30/2016			
2		28 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M004	07/30/2016			

Labeler - Compania Internacional de Comercio, S.A.P.I de C.V. (822165213)

Establishment						
Name	Address	ID/FEI	Business Operations			
Compania Internacional de Comercio, S.A.P.I de C.V.		822165213	manufacture(54312-019)			

Compania Internacional de Comercio, S.A.P.I de C.V.

Revised: 10/2023