

BACITRACIN ZINC- bacitracin zinc ointment
Promex, LLC

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)

Bacitracin Zinc 500 units

Purpose

First aid antibiotic

Uses

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

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites

When using this product

- do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

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

Keep out of reach of children

In case of accidental Ingestion, seek professional assistance or contact a Poison Control Center immediately.

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 20 - 25C (68 - 77F)

Inactive ingredients

light mineral oil, white petrolatum

Package label

Drug Facts	Información del Medicamento
Active ingredients (in each gram) Purposes Bacitracin Zinc 500 units.....First aid antibiotic	Ingredientes activos (por gramo) Propósito Bacitracina Zinc 500 Unidades..... Antibiótico de primeros auxilios
Uses First aid to help prevent infection in minor: ■ cuts ■ scrapes ■ burns	Usos Primeros auxilios para prevenir infecciones menores: ■ cortadas ■ quemaduras ■ raspaduras
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	Advertencias Para uso externo solamente No utilice ■ en los ojos ■ en grandes áreas del cuerpo ■ en caso de alergia a alguno de los ingredientes
Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites	Consulte a su médico antes de usar si ■ usted tiene punzones o heridas profundas ■ mordeduras de animales
When using this product ■ do not use longer than 1 week unless directed by a doctor	Cuando use este producto ■ no exceda el uso por más de 1 semana a menos que lo indique un médico
Stop use and ask a doctor if ■ condition persists or gets worse ■ a rash or other allergic reaction occurs	Suspenda el uso y pregúntele a un doctor si: ■ la condición permanece o empeora ■ una erupción u otra reacción alérgica se produce
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda profesional o contacte un Centro de toxicológica inmediatamente.
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	Modo de empleo ■ Limpie area afectada ■ aplique una pequeña cantidad (equivalente a la superficie de la punta de un dedo) aplique de 1 a 3 veces al día. ■ se puede cubrir con un vendaje esterilizado
	Información Adicional guarde a 20 - 25C (68 - 77F)
	Ingrediente inactivo aceite mineral ligero, petrolato blanco

Drug Facts (continued)
Other information ■ store at 20 - 25C (68 - 77F)
Inactive ingredients light mineral oil, white petrolatum

Made in Korea / Fabricado en Corea



Pro-Mex® Miami, FL 33179 Questions Comments?
1 (305) 653-2700

28.35 g. (1 oz)

First Aid Antibiotic / Antibiótico de Primeros Auxilios

T-RAPHEL

LOT & EXP.

Pro-Mex®

First Aid Antibiotic / Antibiótico de Primeros Auxilios

T-RAPHEL

Pro-Mex®

Bacitracin ointment 1 oz package

BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP ^U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0031-1	1 in 1 CARTON		
1		28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	12/02/2013	

Labeler - Promex, LLC (789974388)

Revised: 12/2013

Promex, LLC