

BIOTIC-PLUS- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine ointment
Provision Medical

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.

TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT.

advanced Stops Pain and Prevents Infection for Cuts and Scrapes

BIOTIC-PLUS 0.5g

Active ingredients

(in each gram)

Bacitracin zinc (400 units Bacitracin)

Neomycin sulfate (3.5 mg neomycin)

Polymyxin B sulfate (5000 units)

Lidocaine .40 mg

Purpose

First Aid Antibiotic

First Aid Antibiotic

First Aid Antibiotic

Anesthetic

Uses

First aid to help prevent infection and provide temporary relief in minor cuts, scrapes, and burns

The Provision First Aid Line

Manufactured for Provision Medical Products Palm Desert, CA 92211

Warnings

For external use only.

Keep out of reach of children

If ingested, contact a Poison Control Center directly.

Do not use

- in eyes or over large areas of the body
- more than 1 week unless directed by a doctor
- if allergic to ingredients.

Stop use, ask a doctor

- in case of deep or puncture wounds, animal bites or serious burns
- if conditions worsen or last more than 7 days
- if rash or allergic reaction occurs

Directions

- adults & children 2 years & older: clean affected area, apply amount (equal to surface area of a tip of finger) on area 1-3 times daily. May be covered with a sterile bandage.
- children under 2: do not use, ask a doctor

Inactive ingredients

white petrolatum

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BIOTIC-PLUS **0.5g**

<p>Manufactured for: Provision Medical Products Palm Desert, CA 92211</p> 	<p>Active ingredient (in each gram)</p> <p>Bacitracin zinc (400 units bacitracin)</p> <p>Neomycin sulfate (3.5 mg neomycin)</p> <p>Polymyxin B sulfate (5000 units)</p> <p>Lidocaine (40 mg)</p>	<p>Purpose</p> <p>First Aid Antibiotic</p> <p>First Aid Antibiotic</p> <p>First Aid Antibiotic</p> <p>Anesthetic</p>
	<p>Use First aid to help prevent infection and for temporary pain relief in minor cuts, scrapes, and burns. ▶</p>	

<p>EXP. LOT</p>	<p>Inactive ingredients white petrolatum</p>	<p>Warnings For external use only. Keep out of reach of children If ingested, contact a Poison Control Center directly. Do not use ■ in eyes or over large areas of the body ■ more than 1 week unless directed by a doctor ■ if allergic to ingredients. Stop use, ask a doctor ■ in case of deep or puncture wounds, animal bites or serious burns ■ if conditions worsen or last more than 7 days ■ if rash or allergic reaction occurs</p> <p>Directions ■ adults & children 2 years & older: clean affected area, apply amount (equal to surface area of a tip of finger) on area 1-3 times daily. May be covered with a sterile bandage. ■ children under 2: do not use, ask a doctor.</p>
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69103-2400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bacitracin zinc (UNII: 89Y4M234ES) (bacitracin - UNII:58H6RWO52I)	bacitracin	400 [iU] in 1 g
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:I16QD7X297)	neomycin	3.5 mg in 1 g
polymyxin b sulfate (UNII: 19371312D4) (polymyxin b - UNII:J2VZ07J96K)	polymyxin b	5000 [iU] in 1 g
lidocaine (UNII: 98PI200987) (lidocaine - UNII:98PI200987)	lidocaine	.40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-2400-1	0.5 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	07/24/2014	

Labeler - Provision Medical (036936831)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-2400)

Revised: 7/2014

Provision Medical