

WELLY BRAVERY TRIPLE ANTIBIOTIC WITH PAIN RELIEF- bacitracin zinc, polymyxin b sulfate, neomycin sulfate, pramoxine hcl ointment

Welly Health PBC

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 ingredients (In each gram)

Bacitracin 500

Neomycin 3.5 mg

Polymyxin B 10,000 units

Pramoxine HCL 10 mg/g

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Pain reliever

Uses

First aid to help prevent infection and temporarily relieves pain due to minor:

- cuts
- scrapes
- burns

Warnings

For external use only

Allergy alert:

- do not use if you are allergic to any of the ingredients

Do not use

- in or near the eyes
- on large areas of the body

Consult a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use longer than 1 week

Stop use and consult a doctor if

- condition persists or gets worse
- symptoms last for more than 7 days or clear up and come back within a few days
- 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 immediately.

Directions

- Adults and children 2 years of age and older
- clean the affected area
- apply a small amount (equal to surface area of tip of finger) on the area 1 to 3 times daily.
- may be covered with a sterile bandage
- Children under 2 years of age; ask a doctor

Other information

- Store at a controlled room temperature 68°-77°F (20°-25°C)

Inactive ingredient

Petrolatum

Questions? 1-833-BE-WELLY**Principal Display Panel -Tube**

Welly First aid NDC 72663-161-60

Triple Action First Aid Antibiotic & Pain Relieving Ointment

NET WT 0.5 oz (14g)

Bacitracin Zinc, Neomycin Sulfate, Polymixin B Sulfat, Pramoxine HCL

welly™
FIRST AID

TRIPLE ACTION
FIRST AID ANTIBIOTIC
& PAIN RELIEVING
OINTMENT

NET WT 0.50 oz (14 g)

Bacitracin Zinc, Neomycin Sulfate,
Polymyxin-B Sulfate, Pramoxine HCl

Active ingredients (in each gram)

Bacitracin 500 Units, Neomycin 3.5 mg, Polymyxin B 10,000 Units First aid antibiotic
Pramoxine HCl 10 mg Pain reliever

Uses: Helps prevent infection in and temporarily relieves pain due to 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 • serious burns. **Stop use and ask a doctor if** • you need to use longer than 1 week • condition persists or gets worse • symptoms persist for more than 1 week, or clear up and occur again within a few days • rash or other allergic reaction develops. **Keep out of the reach of children.** If swallowed get medical help or contact a Poison Control Center immediately. **Directions:**

• Adults and children 2 years and older: • clean affected area • apply a small amount (equal to the surface area of tip of finger) on area 1 to 3 times daily. • may be covered with a sterile bandage.

Children under 2 years: ask a doctor. **Other information:** Store at a controlled room temperature

68°-77°F (20°-25°C) **Distributed by: Welly Health PBC Minneapolis, MN 55402 1-833-BE-WELLY**

Purpose

Principal Display Panel - Case

Drug Facts

Active Ingredients (in each gram)

Bacitracin, Zinc 500 Units First aid antibiotic
Neomycin Sulfate 3.5 mg First aid antibiotic
Polymyxin B Sulfate 10,000 Units First aid antibiotic
Pramoxine Hydrochloride 10 mg Pain reliever

Uses Helps prevent infection in and temporarily relieves pain due to 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.

Purpose

welly™
FIRST AID
Bravery Balm+
TRIPLE ACTION FIRST AID
ANTIBIOTIC / PAIN RELIEVING
OINTMENT



NET WT 0.50 oz (14 g)
Bacitracin Zinc, Neomycin Sulfate,
Polymyxin B Sulfate, Pramoxine HCl

Recycle me!
Welly™ www.GetWelly.com
Minneapolis, MN 55402
1-833-BE-WELLY
Products of USA with globally sourced materials RK18SHE

WLY1022



Warnings continued
Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns. **Stop use and ask a doctor if** • you need to use longer than 1 week • condition persists or gets worse • symptoms persist for more than 1 week, or clear up and occur again within a few days • rash or other allergic reaction develops. **Keep out of the reach of children.** If swallowed get medical help or contact a Poison Control Center immediately.

Directions Adults and children 2 years and older: • clean affected area • apply a small amount (equal to the surface area of tip of finger) on area 1 to 3 times daily. • may be covered with a sterile bandage. Children under 2 years: ask a doctor

Other information • Store at a controlled room temperature 68°-77°F (20°-25°C)

Inactive ingredient Petroleum

Welly Bravery Balm First Aid NDC 72663-161-60

Bravery Balm

Triple Action First aid Antibiotic & Pain Relieving Ointment

NET WT 0.50 oz (14g)

Bacitracin Zinc, Neomycin Sulfate, Polymyxin B Sulfate, Pramoxine HCL



WELLY BRAVERY TRIPLE ANTIBIOTIC WITH PAIN RELIEF

bacitracin zinc, polymyxin b sulfate, neomycin sulfate, pramoxine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72663-161
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	500 [USPU] in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B	10000 [USPU] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:I16QD7X297)	Neomycin	3.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 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:72663-161-60	1 in 1 CASE	01/31/2019	

1	14 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 final	part333B	01/31/2019	

Labeler - Welly Health PBC (116766884)

Registrant - Welly Health PBC (116766884)

Establishment			
Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(72663-161)

Revised: 2/2019

Welly Health PBC