

**WATER-JEL 3-IN-1 ANTIBIOTIC- bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment**

**Water-Jel Technologies**

*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.*

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**Triple Antibiotic Ointment**

**Active ingredients (each gram contains)**

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

**Purpose**

First aid antibiotic

First aid antibiotic

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 or 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**

- a deep or puncture wounds, animal bites, or serious burns

**Stop use and ask a doctor if**

**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 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 15 ° to 25 °C (59 ° to 77 °F)
- tamper evident sealed packets
- do not use any opened or torn packets
- you may report a serious adverse reaction to this product to 800 275-3433

**Inactive ingredient**

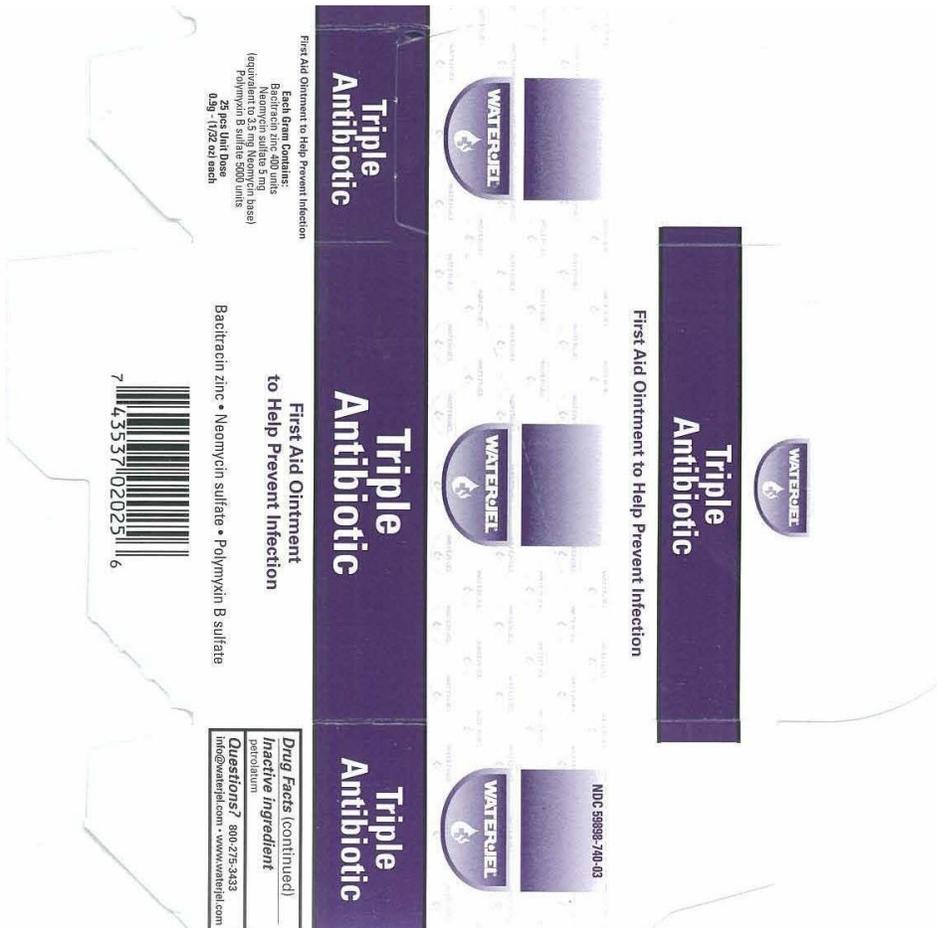
petrolatum

**Questions or comments?**

**800-275-3433**

info@waterjel.com www.waterjel.com

**Principal Display Panel**



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# WATER-JEL 3-IN-1 ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59898-740
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	417.8 [iU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5322.8 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 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:59898-740-02	144 in 1 BOX, UNIT-DOSE	03/30/2010	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59898-740-03	25 in 1 BOX, UNIT-DOSE	03/30/2010	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:59898-740-01	1728 in 1 CARTON	03/30/2010	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:59898-740-38	1728 in 1 CARTON	03/30/2010	
4		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:59898-740-34	0.9 g in 1 PACKET; Type 0: Not a Combination Product	03/30/2010	
6	NDC:59898-740-36	0.5 g in 1 PACKET; Type 0: Not a Combination Product	03/30/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/30/2010	

**Labeler** - Water-Jel Technologies (155522589)

## Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-740)

