

**RECELLTIS- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hcl cream**  
**CellNovation Technology Corporation**

*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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**ReCellTis**

**ReCellTis +Pain & Itch Relief First Aid Cream**

**Drug Facts**

**Active Ingredients (in each gram)**

Bacitracin Zinc 400 units

Neomycin Sulfate 5mg (equivalent to 3.5 mg of neomycin base)

Polymyxin B Sulfate 5,000 units

Lidocaine Hydrochloride 20 mg

**Purpose**

First aid antibiotic

First aid antibiotic

First aid antibiotic

Local anesthetic

**Uses**

First aid to prevent infection, for temporary relief of pain or discomfort, and helps promote skin repair in minor:

- Cuts
- Scrapes
- Burns

**Warnings**

For external use only

**Do not use**

- in the eyes
- if you are allergic to any of the ingredients
- over large areas of the body

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

Keep out of reach of children.

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

### **Directions**

Adults and children 2 years of age or older:

- clean the affected area
- apply a small amount (thin layer) on the area 1 to 3 times daily
- may be covered with sterile bandage

Children under 2 years of age: ask a doctor

### **Other Information**

- store at 15° to 30°C (59° to 86°F)
- protect from freezing and avoid excessive heat

### **Inactive ingredients**

Carboxymethyl Cellulose, Cetostearyl Alcohol, Cetyl Alcohol, CoEnzyme Q-10, Purified Water, Phenoxyethanol, Polysorbate 80, Sorbitan Oleate, Tocopheryl Acetate , White Petrolatum, Zinc Gluconate.

### **PRINCIPAL DISPLAY PANEL**

**MAXIMUM STRENGTH**

Helps Minimize Scarring  
24 Hour Antibiotic Protection  
Bacitracin, Neomycin Sulfate,  
Polymyxin-B Sulfate, Lidocaine



Cuts, Burns & Scrapes

**ReCellTis**

+PAIN & ITCH RELIEF

FIRST AID CREAM

+PAIN & ITCH RELIEF

**ReCellTis**

THE ONLY FIRST AID CREAM THAT HELPS PREVENT INFECTION  
AND PROMOTES SKIN REPAIR.

NET WT 1 oz (28 g)



FIRST AID CREAM

**ReCellTis**  
+PAIN & ITCH RELIEF

**ReCellTis**

+PAIN & ITCH RELIEF

THE ONLY FIRST AID CREAM THAT HELPS PREVENT INFECTION AND PROMOTES SKIN REPAIR.

MADE IN MEXICO

Distributed by CellNovation Technology Corp.

NDC# 71929-069-32

USA Innovation



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<p><b>Drug Facts</b> (continued)</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>you need to use longer than 1 week</li> <li>rash or other allergic reaction develops</li> <li>condition persists or gets worse</li> <li>keep out of reach of children.</li> </ul> <p><b>Purpose</b></p> <p>Local anesthetic: Lidocaine Hydrochloride 20 mg.</p> <p>First aid antibiotic: Polymyxin B Sulfate 5,000 units.</p> <p>First aid antibiotic: Neomycin Sulfate 5mg (equivalent to 0.5 mg of neomycin base).</p> <p>First aid antibiotic: Bacitracin Zinc 400 units.</p> <p><b>Directions</b></p> <p>Adults and children 2 years of age or older:</p> <ul style="list-style-type: none"> <li>clean the affected area.</li> <li>apply a small amount (thin layer) on the area 1 to 3 times daily.</li> <li>may be covered with a sterile bandage.</li> </ul> <p>Children under 2 years of age: ask a doctor.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 15° to 30° C (59° to 86° F)</li> <li>protect from freezing and avoid excessive heat.</li> </ul> <p><b>Inactive ingredients:</b> Cellulose Carbonylmethyl, Cetostearyl Alcohol, Cetyl Alcohol, Coenzyme Q-10, Purified Water, Phenylethanol, Polysorbate 80, Sorbitan Oleate, Tocopheryl Acetate, White Petrolatum, Zinc Gluconate.</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each gram)</b></p> <p><b>Local anesthetic:</b> Lidocaine Hydrochloride 20 mg.</p> <p><b>First aid antibiotic:</b> Polymyxin B Sulfate 5,000 units.</p> <p><b>First aid antibiotic:</b> Neomycin Sulfate 5mg (equivalent to 0.5 mg of neomycin base).</p> <p><b>First aid antibiotic:</b> Bacitracin Zinc 400 units.</p> <p><b>Uses:</b> First aid to prevent infection, for temporary relief of pain or discomfort, and helps promote skin repair in minor: Cuts ■ Scrapes ■ Burns</p> <p><b>Warnings</b></p> <p>For external use only.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>in the eyes</li> <li>if you are allergic to any of the ingredients</li> <li>over large areas of the body.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>deep or puncture wounds</li> <li>animal bites</li> <li>serious burns</li> </ul>
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bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hcl cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71929-069
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [USP'U] 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 [USP'U] in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	20 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
COENZYME Q10, (2Z)- (UNII: U705VLF0VW)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71929-069-32	28 g in 1 TUBE; Type 0: Not a Combination Product	03/21/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/21/2018	

**Labeler** - CellNovation Technology Corporation (080976562)