RECELLTIS WOUND CREAM- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hcl cream
CellNovation Technology

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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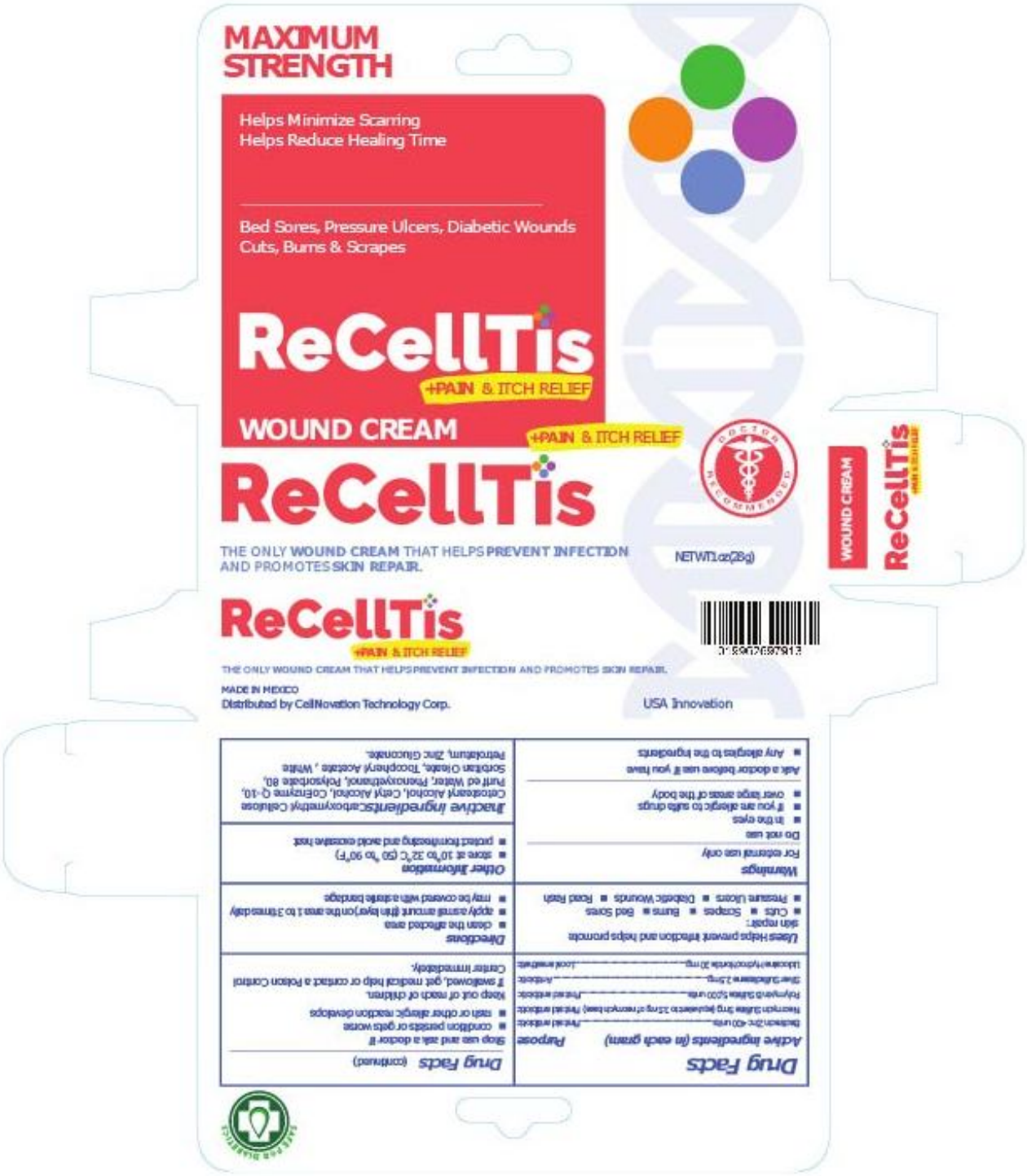
recelltis wound 1oz tube in box

Drug Facts



Active ingredients (in each gram)

Bacitracin Zin 400 units

Neomycin Sulfate 5mg

Polymyxin B Sulfate 5,000 units

Lidocaine Hydrochloride 20mg

Uses

Helps prevent infection and helps promote skin repair:
- Cuts
- Scrapes
- Burns
- Bed Sores
- Pressure Ulcers
- Diabetic Wounds
- Road Rash

Warnings

For external use only

Do Not Use
- In the eyes
- Over large areas of the body

Ask a Doctor Before Use If You Have
- Any allergies to the ingredients

Stop Use and Ask A Doctor If
- condition persists or gets worse
- rash or other allergic reaction develops

Keep out of reach of children.

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

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

Other Information
- store at 10° to 32C (50° to 90°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

RECELLTIS WOUND CREAM

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71929-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	600 mg in 30 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	150000 [USP'U] in 30 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	12000 [USP'U] in 30 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	105 mg in 30 g

Inactive Ingredients	
Ingredient Name	**Strength**
SILVER (UNII: 3M4G523W1G)	25 mg in 30 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71929-070-28	28 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	06/01/2019	

Labeler - CellNovation Technology (080976562)

Registrant - CellNovation Technology (080976562)

Establishment

Name	Address	ID/FEI	Business Operations
Monarch PCM, LLC		080000294	manufacture(71929-070)

Revised: 12/2021 CellNovation Technology