MIRAKEL PAIN RELIEF ROLL-ON- lidocaine hcl gel
Sanvio, Inc.

Mirakel Pain Relief Roll-On

Lidocaine HCl 4%

Topical anesthetic

Temporarily relieves minor pain.

For external use only.

Flammable--keep away from fire or flame.

Do not use

- if you have an allergic reaction to lidocaine or other local anesthetics
- on large areas of the body or on cut, irritated, blistered, or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

Stop use and ask a doctor if

- condition worsens
- severe burning sensation, redness, rash, or irritation develops
- symptoms persist for more than 7 days or clear p and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breastfeeding, ask a health professional before use.

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

Clean affected area before applying product. **Adults and children 12 years and older**: apply to the affected area not more than 3 to 4 times daily. **Children under 12 years old:** ask a doctor.

Water, Alcohol Denat., Glyceryl Stearate, Cetearyl Alcohol, Dimethicone, Aminomethyl Propanol, Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Salix Alba (Willow) Bark Extract, Curcuma Longa (Turmeric) Root Extract, Mentha Piperita (Peppermint) Leaf Extract, Eucalyptus Globulus Leaf Oil, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Ceteth-20 Phosphate, Dicetyl Phosphate, Disodium EDTA, Ethylhexylglycerin, Steareth-21, Methylparaben

MIRAKEL PAIN RELIEF ROLL-ON

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78589-257
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ALCOHOL (UNII: 3K9958V90M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
TURMERIC (UNII: 856YO1Z64F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78589-257-03	85 g in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/01/2023	

Labeler - Sanvio, Inc. (100812165)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(78589-257)

Revised: 1/2024 Sanvio, Inc.