MIRAKEL PAIN AND ITCH RELIEF- benzocaine 20%, resorcinol 3% cream
Sanvio, Inc.

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.

Mirakel Max Strength Pain and Itch Relief, Benzocaine 20%, Resorcinol 3%

Benzocaine 20%, Resorcinol 3%

Topical analgesic

For the temporary relief of minor aches and pain associated with minor burns, minor skin irritations, minor cuts, insect bites or stings, scrapes, and sunburns.

For external use only. Do not use over large areas of the body. **Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics. **When using this product** avoid contact with eyes, use only as directed. **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days, symptoms clear up and occur again within a few days, itching, rash or irritation develops.

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

Adults and children 2 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 2 years of age: ask a doctor.

Water, mineral oil, cetyl alcohol, propylene glycol, glyceryl stearate, PEG-100 stearate, isopropyl palmitate, ocimum basilicum (basil) leaf extract, chamomilla recutita (matricaria) flower extract, calendula officinalis flower extract, chrysanthemum parthenium (feverfew) extract, melia azadirachta leaf extract, glycerin, tocopheryl acetate, aloe barbadensis leaf extract, retinyl palmitate, cholecalciferol, mentha piperita (peppermint) oil, zea mays (corn) oil, isopropyl myristate, carbomer, triethanolamine, lanolin, disodium EDTA, sodium sulfite, methylparaben.

MIRAKEL PAIN AND ITCH RELIEF

benzocaine 20%, resorcinol 3% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78589-233
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BASIL (UNII: 2U0KZP0FDW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
FEVERFEW (UNII: Z64FK7P217)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CORN OIL (UNII: 8470G57WFM)	
TROLAMINE (UNII: 9O3K93S3TK)	
LANOLIN (UNII: 7EV65EAW6H)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78589-233-02	95 g in 1 TUBE; Type 0: Not a Combination Product	07/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/11/2022	

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(78589-233)

Revised: 11/2022 Sanvio, Inc.