

MIRAKEL- benzocaine 10%, resorcinol 1.5% 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.

Sanvio Mirakel Cream

Active Ingredients

Active ingredients Purpose

Benzocaine 10%External Analgesic

Resorcinol 1.50%.....External Analgesic

<i>Active ingredients</i>	<i>Purpose</i>
Benzocaine 10%	External Analgesic
Resorcinol 1.50%	External Analgesic

Uses

Uses temporary relief of pain, itching and discomfort associated with:

- rashes
- minor cuts
- minor burns
- minor skin irritations
- insect bites

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■ rashes	■ minor burns	■ insect bites
■ minor cuts	■ minor skin irritations	

Warnings

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For external use only

When using this product ■ avoid contact with eyes ■ do not apply over large areas of the body

Stop use and ask a doctor if ■ condition worsens or symptoms persist for more than 7 days, or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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Keep Out Of Reach of Children

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Directions

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■ **adults and children 12 years and older:** apply small amount to affected area not more than 3-4 times a day.

■ **children under 12 years of age:** consult a doctor.

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Other Information

Other Information ■ store at 20-25°C (68-77°F)
■ skin is more sensitive to sunlight when using this product.
■ keep tightly closed after use.

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Inactive Ingredients

Inactive ingredients aloe barbadensis (aloe vera) leaf extract, butylated hydroxytoluene, carbomer, cetyl alcohol, cholecalciferol, edetate disodium, glyceryl monostearate, isopropyl palmitate, maltodextrin, mentha piperita (peppermint) oil, methylparaben, mineral oil, PEG-40 hydrogenated castor oil, PEG-100 stearate, petrolatum, propylene glycol, propyl-paraben, purified water, retinyl palmitate, sodium lauryl sulfate, thymus vulgaris (thyme) flower leaf oil, tocopheryl acetate triethanolamine, xanthan gum.

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Questions

Questions? Call 1-888-855-5681

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Principal Display Panel

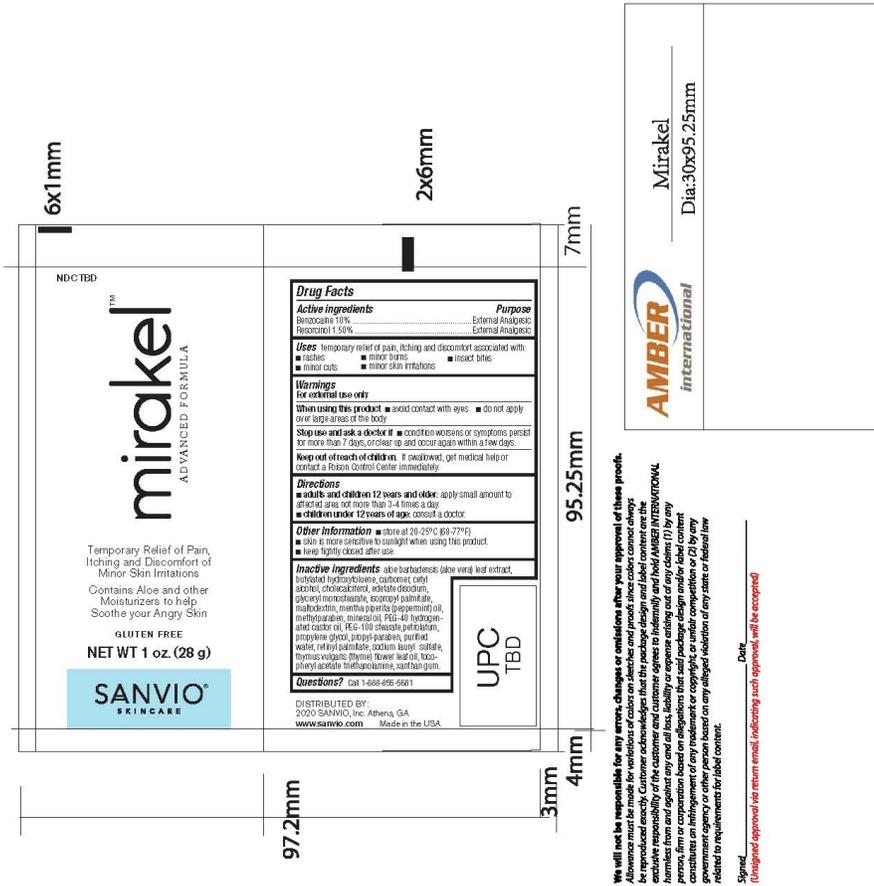
SANVIO
MIRAKEL CREAM 1OZ
Tube

● PROOF 1a Date Feb. 28.20
○ FINAL ART

INKS

● PMS 2975 ● Black

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DOCUMENT AT 100%



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Signed: _____ Date: _____
(Original approval via return email, indicating such approval, will be accepted)

MIRAKEL			
benzocaine 10%, resorcinol 1.5% cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78589-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.1 g in 1 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	0.03 g in 1 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78589-100-01	1 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78589-100-02	1 g in 1 BOX; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2020	

Labeler - Sanvio, Inc. (100812165)**Registrant** - Sanvio, Inc. (100812165)**Establishment**

Name	Address	ID/FEI	Business Operations
Sanvio, Inc.		100812165	manufacture(78589-100)

Revised: 7/2020

Sanvio, Inc.