

MIEL ROSADA- sodium borate, glycerin solution
Dannso Corp./d.b.a. Essential Products

Miel Rosada

☐ Active Ingredients

Purpose

SODIUM BORATE Antifungal

Glycerin Moisturizer

☐ Use

May help alleviate mouth ulcers

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

Antifungal

For External Use Only

☐ Directions

- clean the affected area
- and dry thoroughly. Apply a thin layer 1 to 3 times daily.
- May be covered with a sterile bandage, let dry first.
- Children under 2 years should consult a physician.

☐ Warnings For external use only

Avoid Contact with eyes.

When using this product

- do not use on irritated skin, in or near eyes or mucous membranes, on wounds or damaged skin, if prone to allergic reaction
- Fatal if swallowed.

Stop use and ask a doctor if condition persists or gets worse

☐ Inactive Ingredients Extract of Roses, Honey , FD&C red # 40, Purified Water



MIEL ROSADA

sodium borate, glycerin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70242-127
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BORATE (UNII: 91MBZ8H3QO) (BORATE ION - UNII:44OAE30D22)	SODIUM BORATE	0.1 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HONEY (UNII: Y9H1V576FH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-127-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M022	01/01/2015	
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Labeler - Dannso Corp./d.b.a. Essential Products (059741071)

Registrant - Dannso Corp./d.b.a. Essential Products (059741071)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfume, Inc		101312044	MANUFACTURE(70242-127)

Revised: 1/2023

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