

MEDACTIVE ORAL RELIEF- spray spray
Integrate Oral Care, LLC.

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.

Active Ingredient

Glycerin 6% (prediluted)

Purpose

Oral Demulcent

Uses

For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat.

Warnings

Sore Throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly.

If an excessive amount of spray is accidentally swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes.

Keep out of the reach of children.

Directions

Use as needed or as directed by a dentist or doctor.

- **Adults and children 2 years of age and older:** Hold bottle upright. Gently press down on spray and apply directly to affected areas in the mouth, approximately 3-4 times per application. Do not rinse out.
- **Children under 12 years of age:** Should be supervised in the use of this product.
- **Children under 2 years of age:** Consult a dentist or doctor.

Other Information

- Store at room temperature. Safe to swallow.
- Do not use if safety sleeve or label is damaged prior to first use. Do not push down on spray rapidly or excessively, as it may cause blockage.
- You may experience a slight, temporary tingle sensation upon initial use; this is normal and causes no harm.

Inactive Ingredients

dimethicone, EDTA, flavor (includes Spilanthes Extract), poloxamer 407, potassium sorbate, sodium saccharin, sucralose, water, xanthan gum, xylitol

Questions or comments?

Call toll-free **1-866-887-4867** or visit **www.integrateoralcare.com**

Oral Relief **Spray**
 NEW Natural Spring Flavor
 MedActive® Oral Relief **Spray**
 with **ULTRAMULSION®** & **Spilanthes Extract**
 For Relief of Oral Discomfort
Oral Demulcent
 Glycerin 6%
 NDC 49741-1016-1
 1 FL.OZ. (29.5 mL)



MEDACTIVE ORAL RELIEF

spray spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49741-1016

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X)	GLYCERIN	29.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 407 (UNII: TUF2IVW3M2)	1 mg in 1 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	1 mg in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O)	1 mg in 1 mL
EDETIC ACID (UNII: 9G34HU7RV0)	1 mg in 1 mL
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	1 mg in 1 mL
WATER (UNII: 059QF0KO0R)	1 mg in 1 mL
XYLITOL (UNII: VCQ006KQ1E)	1 mg in 1 mL
XANTHAN GUM (UNII: TTV12P4NEE)	1 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	1 mg in 1 mL

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
FRUIT (Natural Spring)	
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741-1016-1	29.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/31/2015	

Labeler - Integrate Oral Care, LLC. (063540457)

Registrant - Integrate Oral Care, LLC. (063540457)