

**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.*

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**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 or 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](http://www.integrateoralcare.com)**



NEW Vanillamint Flavor  
 MedActive® Oral Relief **Spray**  
 with **ULTRAMULSION® & Spilanthes Extract**  
**For Relief of Oral Discomfort**  
**Oral Demulcent**  
**Glycerin 6%**  
**NDC 49741-101901**  
 1 FL. OZ. (29.5mL)

**MEDACTIVE ORAL RELIEF**  
 spray spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49741-1019
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	VANILLA (Vanillamint)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741-1019-1	30 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)