

MEDACTIVE ORAL RELIEF- lozenge lozenge **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 (in each lozenge)

Pectin 2.8 mg

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.

Keep out of the reach of children.

Directions

Use as needed, up to 8 lozenges per day, or as directed by a dentist or doctor.

- **Adults and children 2 years of age and older:** Allow lozenge to dissolve slowly in the mouth. For optimal effect, intermittently position lozenge under the tongue. Do not swallow whole. Do not chew.
- **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.
- You may experience a slight, temporary tingle sensation upon initial use; this is normal and causes no harm.

Inactive Ingredients

acesulfame potassium, citric acid, dimethicone, FD&C Yellow No. 6, flavor (includes Spilanthes Extract), isomalt, malic acid, poloxamer 338, sucralose, water.

Questions or comments?

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



MedActive® Oral Relief Lozenges
 For Relief of Oral Discomfort
 with **ULTRAMULSION® & Spilanthes Extract**
Orange Crème
Oral Demulcent
 Pectin 2.8mg
 NDC 49741-1011-2
20 Lozenges

MEDACTIVE ORAL RELIEF

lozenge lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49741-1011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PECTIN (UNII: 89NA02M4RX) (PECTIN - UNII:89NA02M4RX)	PECTIN	2.8 mg

Inactive Ingredients

Ingredient Name	Strength
ISOMALT (UNII: S870P5502W)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
MALIC ACID (UNII: 817L1N4CKP)	
POLOXAMER 338 (UNII: F75JV2T505)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange (Translucent Orange)	Score	no score
Shape	OVAL	Size	22mm
Flavor	ORANGE (Orange Crème)	Imprint Code	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741-1011-2	20 in 1 BOX	08/31/2015	
1	NDC:49741-1011-1	1 in 1 CELLO PACK; Type 0: Not a Combination Product		

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)

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Integrate Oral Care, LLC.