# 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.

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# **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.

**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 symptons 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 or age: Should be supervised in the use of this product.
- Children under 2 years of age: Consult a dentist or doctor.

### Other Information

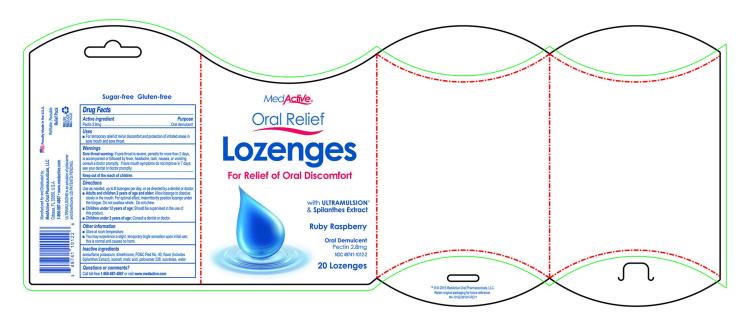
- Store at room temperature.
- You may experience a slight, temporary tingle sensation upon initial use; this is normal and causes no harm.

# **Inactive Ingredients**

acesulfame potassium, dimethicone, FD&C Red No. 40, 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

Ruby Raspberry

# **Oral Demulcent**

Pectin 2.8mg

NDC 49741-1012-2

# 20 Lozenges

# **MEDACTIVE ORAL RELIEF**

lozenge lozenge

<b>Product Information</b>	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49741-1012
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MALIC ACID (UNII: 817L1N4CKP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

ISOMALT (UNII: S870P55O2W)	
POLOXAMER 338 (UNII: F75JV2T505)	
WATER (UNII: 059QF0KO0R)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	

Product Characteristics			
Color	red (Translucent Light Red)	Score	no score
Shape	OVAL	Size	22mm
Flavor	RASPBERRY (Ruby Raspberry)	Imprint Code	None
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741- 1012-2	20 in 1 BOX	08/31/2015	
1	NDC:49741- 1012-1	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)

Revised: 12/2022 Integrate Oral Care, LLC.