

ORCA PAIN RELIEVER PUTTY WITH MENTHOL- menthol paste
ORCA Products, LLC

ORCA Pain Reliever Putty with Menthol

Drug Facts

Active ingredient

Menthol 1.6%

Purpose

oral pain reliever

Use

- for the temporary relief of pain due to minor irritation or injury of the mouth and gums

Warnings

Do not use

- this product for more than 7 days unless directed by a dentist or doctor.

When using this product

- do not exceed recommended dosage.

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Allow product dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor

- Children under 12 years of age: Consult a dentist or doctor.

Other information

- Do not use if outer package is broken, cut or torn.

Inactive ingredients

Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carthamus Tinctorius (Safflower) Seed Oil, Chamomilla Recutita (Matricaria) Flower Extract, Cinnamomum Zeylanicum Bark Oil, Elettaria Cardamomum Seed Oil, Eugenol, Glycerin, Glyceryl Caprylate, Glyceryl Undecylenate, Guaiacol, Maltodextrin, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Xanthan Gum, Xylitol

Questions?


1-970-401-1138 MON-FRI 8 AM to 3 PM (CST)

Package Labeling: 82939-001-01

FAST
ACTING
LONG
LASTING

TOOTHACHE • GUM PAIN • ULCERS

BENZOCAINE FREE


 Oral Care Products

**ORAL PAIN
RELIEVER PUTTY**
with menthol

Made with Natural Essential Oils

6.75

8 Doses

Net Wt. 0.25 oz (7 g)


 Oral Care Products

ORAL PAIN RELIEVER PUTTY
with menthol
 Made with Natural Essential Oils

• Doesn't Run or Drip • Relieves Pain in Minutes • Safe •
 • Clinically Proven • Stays in Place to Directly Target Pain •


 When using ORCA Oral Pain Reliever Putty patients saw an average pain reduction from 7.5/10 to 0.5/10 in 9 minutes. ¹


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Portion of Putty in Use
 For best results, avoid drinking or eating for at least one hour after applying product. Rinsing, brushing slightly before use may allow easier manipulation.



Additional Instructions: Make sure hands are washed and clean. • Open jar by rotating cap counter clockwise. • Utilize enclosed spatula to remove a pea sized amount of ORCA Pain Reliever Putty. • Remove the putty from the spatula with slightly wetted fingers. • Press putty along gum line of affected tooth—using the tackiness of the material to engage regions between teeth to hold in place (see diagram for example). • For maximum effectiveness, ensure material is along the root line of the tooth. • Allow product to completely dissolve - this may take up to 15 minutes • You may choose to expectorate (spit) due to increased salivation as the taste is quite strong • Wash hands thoroughly after use. • It is recommended to store the jar in its upright position. • Also avoid excessive heat. • Results have shown significant reduction in symptoms within 10 minutes—individual results may vary.

Manufactured for ORCA Products, LLC
 Dothan, AL 36303
 website: www.orca-products.com
 email: info@orca-products.com

Lot No.: _____
 Exp. Date: _____

Visit our website for details of clinical studies.



THIS UNIT NOT LABELED FOR RETAIL SALE



ORCA[®] ORAL PAIN RELIEVER PUTTY

with menthol

TOOTHACHE, GUM PAIN, ULCERS

Net Wt. 0.25 oz (7 g)

ORCA PAIN RELIEVER PUTTY WITH MENTHOL

menthol paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82939-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	8.4 mg in 0.525 g

Inactive Ingredients

Ingredient Name	Strength
CARDAMOM OIL (UNII: JM0KJ091HZ)	
CHAMOMILE (UNII: FGL3685T2X)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	

CLOVE OIL (UNII: 578389D6D0)	
GLYCERIN (UNII: PDC6A3C0OX)	
GUAIACOL (UNII: 6JKA7MAH9C)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
TEA TREE OIL (UNII: VIF565UC2G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82939-001-01	1 in 1 PACKAGE	09/15/2022	12/20/2024
1		4.2 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:82939-001-02	1 in 1 BLISTER PACK	09/15/2022	
2		7 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/15/2022	

Labeler - ORCA Products, LLC (117716283)

Registrant - ORCA Products, LLC (117716283)