# ORCA COMPLETE MENTHOL PAIN RELIEVER- menthol liquid ORCA Products, LLC

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#### **ORCA Complete Menthol Oral Pain Reliever**

## **Drug Facts**

#### Active ingredient

Menthol 2%

#### **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: Place 8-10 drops onto ORCA Foam or similar resorbable gelatin sponge or gauze strip in a sterile fashion and apply to areas of discomfort in oral region. Guaze strip requires removal. Orca Foam soaked sponge will resorb and does not require removal.

- Children under 12 years of age should be supervised in use of this product.
- Children under 12 years of age: Consult a dentist or doctor.

#### Other information

• Do not use if tamperproof seal is not intact at time of first use.

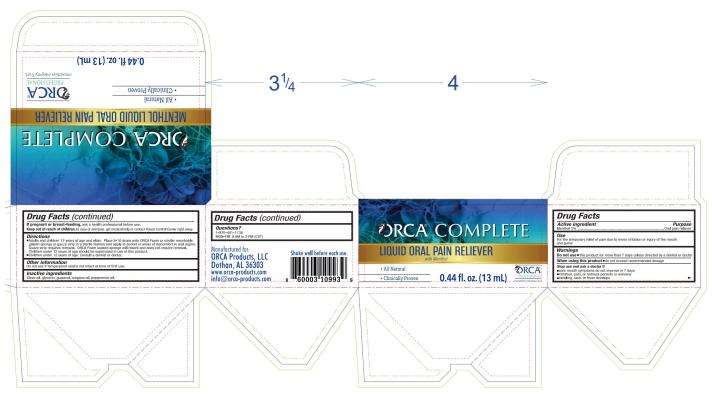
## Inactive ingredients

Clove oil, glycerin, guaiacol, oregano oil, peppermint oil.

#### **Questions?**

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

# Package Labeling: 82939-000-02





# COMPLETE DRY SOCKET

# LIQUID ORAL PAIN RELIEVER

with Menthol

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: PLACE 8-10 DROPS ONTO ORCA FOAM OR SIMILAR RESORBABLE GELATIN SPONGE OR GAUZE STRIP IN A STERILE FASHION AND APPLY TO SOCKET OR AREAS OF DISCOMFORT IN ORAL REGION. GAUZE STRIP REQUIRES REMOVAL. ORCA FOAM SOAKED SPONGE WILL RESORB AND DOES NOT REQUIRE REMOVAL. DO NOT SWALLOW. CHILDREN UNDER 12 YEARS OF AGE: CONSULT A DENTIST OR DOCTOR. DO NOT USE IF TAMPERPROOF SEAL IS NOT INTACT AT TIME OF FIRST USE.

QUESTIONS? 1-970-401-1138 MON-FRI 8am to 3 pm (CST)



Manufactured for:

ORCA Products, LLC Dothan, AL 36303 www.orca-products.com info@orca-products.com

0.44 fl. oz. (13 mL)

## **ORCA COMPLETE MENTHOL PAIN RELIEVER**

menthol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82939-000

**Route of Administration** 

ORAL

<b>Active</b>	Ingredient/Active	Moiety
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Active ingredient/Active Molecy					
Ingredient Name	<b>Basis of Strength</b>	Strength			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	20 mg in 1 mL			

Inactive Ingredients			
Ingredient Name	Strength		
<b>CLOVE OIL</b> (UNII: 578389D6D0)			
GLYCERIN (UNII: PDC6A3C0OX)			
GUAIACOL (UNII: 6JKA7MAH9C)			
OREGANO LEAF OIL (UNII: 7D0CGR40U1)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:82939- 000-01	1 in 1 BOX	09/15/2022	08/31/2025		
1		10 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product				
2	NDC:82939- 000-02	1 in 1 BOX	09/15/2023			
2		13 mL in 1 BOTTLE; 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)

Revised: 12/2023 ORCA Products, LLC