# ORAJEL COLD SORE MOISTURELOCK- benzocaine cream Church & Dwight Co., Inc.

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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# Orajel Cold Sore Moisturelock

Allantoin 0.5%

Benzocaine 20%

Camphor 3%

Dimethicone 2%

Menthol 1%

White petrolatum 64%

Allantoin - Skin protectant

Benzocaine - Topical anesthetic

Camphor - Topical analgesic

Dimethicone - Skin protectant

Menthol - Topical analgesic

White petrolatum - Skin protectant

**Uses** • temporarily relieves pain and dryness; softens crusts (scabs) associated with • cold sores • fever blisters

# For external use only.

**Allergy alert:** do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

**Do not use •** more than directed • for more than 7 days unless directed by a physician

**When using this product** • do not get into eyes

**Stop use and ask a physician if •** conditions worsens • symptoms do not improve in 7 days • symptoms clear up and occur again within a few days • swelling, rash or fever develops • irritation, pain or redness persists or worsens

**Keep out of reach of children.** In case of overdose or allergic reaction, get medical help or contact Poison Control Center right away.

## **Directions**

• squeeze tube to dispense • blend well until green tint disappears • rub in gently

Adults and children 2 years of age and older | Apply to affected area not more than 3 to 4 times daily

Children under 12 years of age | Should be supervised in the use of this product

Children under 2 years of age | Ask a physician

Other information • do not use if the package is torn, cut or otherwise damaged • store at 15-30°C (59-86°) under dry conditions • this is a personal care item and should be used by one individual only

**Inactive Ingredients** caprylic/capric triglyceride, Prunella vulgaris leaf extract. propylene glycol,

water, tocopheryl acetate, retinyl palmitate, Zea mays (corn) oil, tocopherol, cholecalciferol, titanium dioxide, yellow 5 lake, iron oxides, blue 1 lake

**Questions or comments** call us at 800 952 5080 Monday through Friday 9 to 5 ET or visit www orajel com

# Orajel

**Instan Pain Relief** 

FOR COLD SORES

# MOISTURELOCK FORMULA

Helps Speed Healing

# Treats 6 Symptoms:

- 1 Pain
- 2 Itching
- 3 Redness
- 4 Scabbing
- 5 Cracking
- 6 Dryness

# **PLUS**

Helps Minimize Appearance of Cold Sores

Topical Anesthetic/Topical

Analgesic/Skin Protectant

NET WT 0.105 OZ (3g)

MAXIMUM STRENGTH BENZOCAINE

Instant Pain Relief

# Orajel. Colosora

Symptom Treatment

# MoistureLock Cream

TREATS HELPS



Pain Itching **Dryness**  Protect Chapped Lips

TOPPELL ARESTE TE / TOPPELL Markie from Personal

NET WT 0.105 OZ (3g)

# Drug Facts

Active ingredients

Purpose

Aliantoin 0.5% Skin protectant
Benzocalne 20% Topical anesthetic
Camphor 3% Topical analgesic
Dimethicone 2% Skin protectant
Menthol 1% Topical analgesic
White petrolatum 64% Skin protectant

USBS m temporarily relieves pain and dryness; softens crusts (scabs) associated with m cold sores m fever bilisters

# Warnings

For external use only.

Methemoglobinemia waming: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: male, gray, or the colored skin (cyanosis) headache rapid heart rate shortness of breath dizziness or lightneadedness fattque or lack of energy

All tryy nieri: do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzoc line or other "caine" anesthetics

Do not use at more than directed at for more than 7 days unless directed by a physician at for teething at in children under 2 years of age

When using this product in do not get into eyes

Stop use and usk a physician if m condition worsens m symptoms do not improve in 7 days m symptoms clear up and occur again within a few days m swelling, rash or fever develops m irritation, pain or redness persists or worsens

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact Poison Control Center right away

**Directions** a squeeze tube to dispense a blend well until green tint disappears a rub in gently

Adults and children 2 years of age and older Apply to affected area not more than 3 to 4 times daily

Children under 2 years of age Do not use

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Questions? call us at 1-800-952-5880 M-F 9am-5pm ET

Charch & Dwight Co., Inc., Ewing, NJ 08628 USA 0JBC-99882-04 72013503





# ORAJEL COLD SORE MOISTURELOCK

benzocaine cream

# **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-761
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	200 mg in 1 g		
ALLANTO IN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 g		
CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941)	CAMPHOR (NATURAL)	30 mg in 1 g		
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 1 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g		
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	640 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
PRUNELLA VULGARIS LEAF (UNII: 2LW0610U4O)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
CORN OIL (UNII: 8470G57WFM)		
CHOLECALCIFEROL (UNII: 1C6V77QF41)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
TOCOPHEROL (UNII: R0ZB2556P8)		

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-761-01	1 in 1 CARTON	07/01/2016	
1		3 g in 1 TUBE; 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	07/01/2016	

# Labeler - Church & Dwight Co., Inc. (001211952)

Establishment				
Name	Address	ID/FEI	Business Operations	
Accupac		071609663	manufacture(10237-761)	

Revised: 3/2020 Church & Dwight Co., Inc.