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.

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

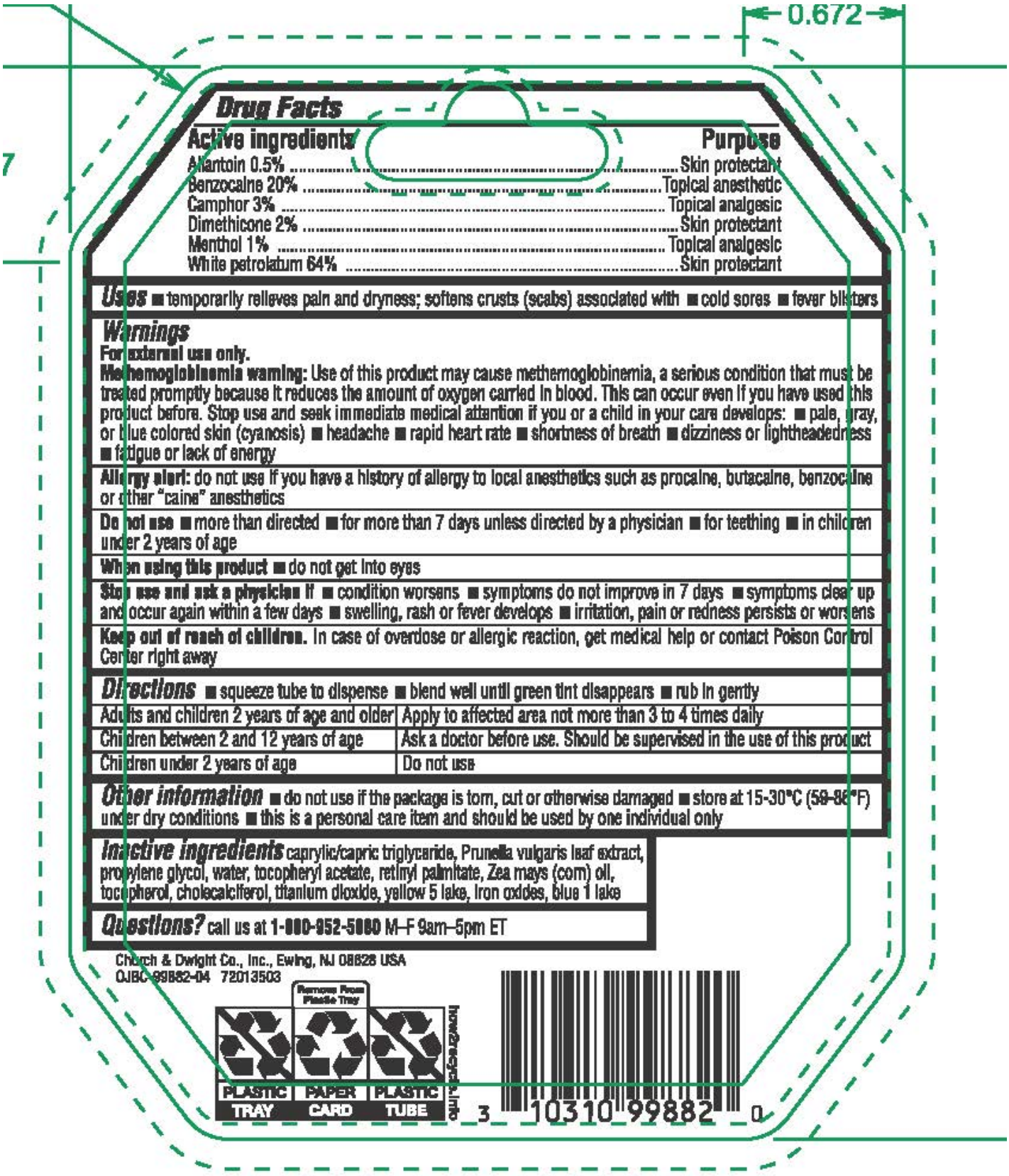
Helps Minimize Appearance of Cold Sores

Topical Anesthetic/Topical

Analgesic/Skin Protectant

NET WT 0.105 OZ (3g)


MAXIMUM STRENGTH BENZOCAINE
Orajel™
Instant Pain Relief
ColdSore
Symptom Treatment
MoistureLock Cream
TREATS
Pain
Itching
Dryness
HELPS
Protect Chapped Lips
Soften Scabs
Mask Redness
NET WT 0.105 OZ (3g)



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
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	30 mg in 1 g
DIMETHICONE (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 DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
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			

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.