

ORAJEL FOR COLD SORES DOUBLE MEDICATED, CREAM- benzocaine and white petrolatum 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 for Cold Sores Double Medicated, Cream

Benzocaine 20%

White petrolatum 73.64%

Questions or comments? call us at **1-800-952-5080** M-F 9am-5pm or visit our website at **www.orajel.com**

Topical anesthetic

Skin protectant

Use temporarily relieves pain, itching and dryness; softens crusts (scabs) associated with • cold sores • fever blisters

Warnings

For external use only

Methemoglobinemia warning: 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: • pale, gray, or blue colored skin (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy

Allergy alert: do not use this product 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 or healthcare provider
- for teething
- in children under 2 years of age

Keep out of reach of children.

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

Directions

- cut open tube of tip on score mark
- Do not use if tip is cut prior to opening

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

Children between 2 and 12 years of age: Ask a doctor before use. Should be supervised

in the use of this product

Children under 2 years of age: Do not use

Inactive ingredients cholecalciferol, mineral oil, phenoxyethanol (and) hydroxyacetophenone (and) caprylyl glycol (and) water, propylene glycol, prunella vulgaris leaf extract, retinyl palmitate (vitamin A palmitate), tocopherol, tocopherol acetate (vitamin E acetate), zea mays (corn) oil

#1

ORAL PAIN

RELIVER

BRAND

FOR ADULTS

2 Active

Ingredients

Orajel

Instant Pain Relief

FOR COLD SORES

Fast-Acting Cream

DOUBLE MEDICATED

Relieves Pain & Itching

Moisturizing Barrier Stays in Place

Paraben Free

TOPICAL ANESTHETIC/SKIN PROTECTANT

NET WT 0.125 OZ (3.5 g)



ORAJEL FOR COLD SORES DOUBLE MEDICATED, CREAM

benzocaine and white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-797
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
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	736.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PRUNELLA VULGARIS FLOWERING TOP (UNII: ID3IB81B1C)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	

CORN OIL (UNII: 8470G57WFM)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-797-12	1 in 1 CARTON	01/18/2021	
1		3.5 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	01/18/2021	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	MANUFACTURE(10237-797)

Revised: 1/2023

Church & Dwight Co., Inc.