ORAJEL COLD SORE TOUCH FREE - SINGLE DOSE- benzalkonium chloride, benzocaine liquid Church & Dwight Co., Inc.

Orajel Cold Sore Touch Free - Single Dose

Drug Facts

Active ingredients

Benzalkonium chloride

Benzocaine

Purpose

Benzalkonium chloride 0.13%	Topical Antiseptic
Benzocaine 5%	Topical Anesthetic

Uses

to treat cold sores/fever blisters

Warnings

For external use only. Flammable, keep away from fire or flame.

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 •in the eyes •over large areas of the body •if you are allergic to any ingredient in this product •more than 3 times per day •longer than 1 week unless directed by a physician •for teething •in children under 2 years of age

Stop use and ask a dentist or physician if •condition persists or worsens •symptoms persist for more than 7 days

Ask a physician if •used to treat deep or puncture wounds, animal bites or serious burns •you are pregnant or nursing a baby

When using this product you may feel a brief stinging when you apply it. The sting should go away in a short time.

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

Directions

•slide-off to remove the protective blue paper cover and slide it on the other end - opposite the white applicator tip •squeeze the vial firmly on the arrow shown on the blue paper cap until you hear it snap •hold with the white applicator tip down to allow the medication to saturate the tip •to minimize pain during application gently touch the site of the cold sore with the saturated applicator tip •Once the area is numb, rub the site of the cold sore and the surrounding area. Rub firmly to allow the treatment to deeply penetrate the skin •to treat most cold sores, multiple treatments may be required •discard after use •for best result ensure that lip area is free of lip preparations, lotions, ointments, residual beverages, or cosmetics, including lipstick

Adults and children 2 years of age and older

Children between 2 and 12 years Ask a doctor before use. Should be supervised in the use of this product

Children under 2 years of age

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Other information

•store at room temperature • the ingredients in toothpaste, soft drinks, and some fruit juices can deactivate the active ingredient in this product •for best results, avoid brushing your teeth with toothpaste or drinking soft drinks or fruit juices for at least one hour after applying the drug •do not use if package is torn, cut or otherwise damaged

Inactive ingredients

isopropyl alcohol (70% v/v), water

Questions or comments?

call us at **1-800-952-5080** M-F 9am-5pm ET or visit our website at <u>www.orajel.com</u>

NEW

LOOK

#1 ORAL PAIN

RELIEF BRAND

FOR ADULTS

BONUS

50% MORE

Orajel™

COLD SORE

PROVIDES IMMEDIATE, TARGETED PAIN RELIEF

LIQUID

FORMULA

TOPICAL ANTISEPTIC

TOPICAL ANESTHETIC

CONTAINS 6 TREATMENT VIALS

NET 0.12 FL OZ (3.5 mL) TOTAL



ORAJEL COLD SORE TOUCH FREE - SINGLE DOSE

benzalkonium chloride, benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-798
Route of Administration	TOPICAL		

Active	Ingred	ient/ <i>P</i>	Active	Moiety	

Ingredient Name Basis of Strength Strength

	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	50 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237- 798-35	6 in 1 PACKAGE	09/01/2021	
1		3.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M016	09/01/2021	
51.00			

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

Revised: 1/2024 Church & Dwight Co., Inc.