ORAJEL FOR COLD SORES SINGLE DOSE- benzalkonium chloride, benzocaine liquid
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 Touch Free, Single Dose

Active ingredients

ACTIVE INGREDIENTS

Benzalkonium chloride, 0.13%

Benzocaine, 5%

Purpose

PURPOSE

Topical Antiseptic

Uses

USES

- to treat cold sores / fever blisters

Warnings

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 beat, 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 one 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 sensation when you apply it. The sting should go away in a short time.

Keep out of reach of children

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

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 results ensure that lip area is free of lip preparations, lotions, ointments, residual beverages, or cosmetics, including lipstick

Adults and children over 2 years of age: Do not use this more than 3 times per day

Children between 2 year 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

OTHER INFORMATION

- Store at room temperature
- **The ingredients in toothpaste, soft drinks, and some fruit juices can deactivate the active ingredient in Orajel Single Dose.**
- For best results, avoid brushing your teeth with toothpaste or drinking soft drinks or fruit juices for one hour after applying the drug.
- Do not use if package is torn, cut or otherwise damaged

Inactive ingredients

INACTIVE INGREDIENTS

isopropyl alcohol (70% v/v), water

Questions or comments?

Questions or comments call us at **1 800 952 5080** Monday through Friday ET or visit our website at www orajel com

Principal Display Panel

Fast-Acting

Orajel™ Instant Pain Relief

Coldsore

Patented Treatment

Topical Antiseptic/

Topical Anethetic

Contains 4 treatment vials

NET 0.08 FL OZ (2.4mL) Total

ORAJEL FOR COLD SORES SINGLE DOSE

benzalkonium chloride, benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-756
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	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**
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-756-04	4 in 1 PACKAGE	07/01/2012	09/30/2024
1		2.4 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:10237-756-03	2 in 1 PACKAGE	07/01/2012	12/18/2019
2		1.2 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 not final	part356	07/01/2012	09/30/2024

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

Revised: 2/2022 Church & Dwight Co., Inc.