

ORAJEL- benzocaine strip

BioFilm

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 Toothache Strips

Benzocaine 15 mg

Menthol 2.5 mg

Benzocaine - Oral Pain Reliever

Menthol - Oral Pain Reliever

Use for the temporary relief of pain due to minor irritation or injury of the mouth and gums

Warnings

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 to the 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 12 years of age

Stop use and ask a physician if • swelling, rash or fever develops • irritation, pain or redness persists or worsens • symptoms do not improve in 7 days • allergic reaction occurs

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 • make sure hands are dry and free of moisture as strip may be sticky/tacky • tear open pouch and remove blue strip

Adults and children 12 years or age and over: Using either side of strip, immediately place directly onto the affected area keeping tongue and lips clear. Gently press for 5-10 seconds until strip adheres to the area. Strip will stay in place and dissolve slowly in mouth for up to 1 hour for duration of treatment. Use up to 4 times daily or as directed by a physician or healthcare provider.

Children under 12 years of age: Do not use

Other Information • do not use if pouch is torn or cut prior to opening • do not use continuously • for best results, avoid drinking warm beverages or eating for at least one hour after applying the product
acid blue 9, glycerin, PEG-8, PEG-90, polycarbophil, potassium sorbate, pullulan, PVP, titanium dioxide, water.

Questions • call us at 800 952 5080 Monday through Friday 9am to 5pm or visit our website at www.oraljel.com

#1 ORAL PAIN

Reliever Brand

For Toothache

NEW!

SLOW DISSOLVING STRIPS

For Lasting Relief

Orajel™

TOOTHACHE STRIPS

MEDICATED FOR TOOTHACHE & GUM

INSTANT & TARGETED PAIN RELIEF

- Long-Lasting Pain Relief
- Maximum level of Pain Relief with 15mg Benzocaine*
- Stays in place for Targeted Relief
- Soothes gums with Menthol

Cool Mint Taste

8 STRIPS

Individually Wrapped

Oral Pain Reliever

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For Toothache

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Cool Mint Taste

8 STRIPS
INDIVIDUALLY WRAPPED
ORAL PAIN RELIEF



Orajel is a trademark of Church & Dwight Co., Inc.
The maker of Orajel™ does not manufacture store
brand oral pain products.
0191-99886-01 2203216

Church & Dwight Co., Inc.
Empg, NJ 08628 USA
Patent Pending



PAPER
MULTI-LAYER
BOOK
WRAPPERS

Great for temporary relief
until you can get to the dentist!

Drug Facts

Active ingredients (in each strip)
Benzocaine 15 mg
Menthol 2.5 mg
Oral pain reliever

Purpose
Use for the temporary relief of pain due to minor irritation or injury of the mouth and gums

Warnings
Mediognabinemia 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 breathing ■ in children under 12 years of age
Stop use and ask a physician if ■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens ■ symptoms do not improve in 7 days ■ allergic reaction occurs
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 ■ make sure hands are dry and free of moisture as strip may be sticky/tacky ■ tear open pouch and remove blue strip
Adults and children 12 years of age and over
Using either side of strip, immediately place directly onto the affected area keeping tongue and lips clear. Gently press for 5-10 seconds until strip adheres to the area.
Strip will stay in place and dissolve slowly in mouth for up to 1 hour for duration of treatment. Use up to 4 times daily or as directed by a physician or healthcare provider.
Children under 12 years of age Do not use

Other information ■ do not use if pouch is torn or cut prior to opening ■ do not use continuously ■ for best results, avoid drinking warm beverages or eating for at least one hour after applying the product

Inactive ingredients acid blue 9, glycerin, PEG-8, PEG-90, polycarboxyl, potassium sorbate, pullulan, PVP, titanium dioxide, water.

Questions? Call us at 1-800-852-5000 M-F 9am-5pm ET or visit our website at www.orajel.com

*per solid form

Orajel
TOOTHACHE STRIPS
MEDICATED FOR TOOTHACHE & GUM
INSTANT & TARGETED PAIN RELIEF

ORAJEL

benzocaine strip

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72337-776
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	25 mg in 1 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
POLYCARBOPHIL (UNII: W25LM17A4W)	
ACID BLUE 9 AMMONIUM (UNII: 86R7G3C26F)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72337-776-01	1 in 1 CARTON	01/15/2019	
1		8 g in 1 PACKAGE; 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	11/05/2018	

Labeler - BioFilm (734555951)

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

Establishment

Name	Address	ID/FEI	Business Operations
Bio Film		734555951	manufacture(72337-776)

Revised: 1/2020

BioFilm