#### DOLODENT MAXIMUM STRENGTH- benzocaine liquid Pharmadel LLC

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## **DoloDent (WP)**

## DRUG FACTS

### **Active ingredient and Purpose**

### Active ingredient Purpose

Benzocaine 20%.....Oral pain reliever

### Uses

For the temporary relief of

- canker sores
- minor injury of the mouth and gums
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances

## 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 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.

Flammable. Keep away from fire or flame. Avoid smoking during application.

#### Do not use

- more than directed
- for more than 7 days unless directed by a dentist or doctor
- for teething
- in children under 2 years of age

## Stop use and ask your doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

## Keep out of reach of children.

If more than used for pain is accidentally swallowed or an allergic reaction occurs, get medical help or contact a Poison Control Center right away.

## Directions

- adults and children 2 years of age and older:
- apply product to a cotton swab or finger to the affected area. Allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor
- children under 12 years of age a should be supervised in the use of the product
- children under 2 years of age: do not use

## Other information

- do not use if clear seal over cap is torn, broken, or missing
- store between 68-77°F (20-25°C)

## Inactive ingredients

alcohol, clove oil, glycerin, polyethylene glycol, propylene glycol, sodium saccharin, sodium methylparaben

## **Questions or comments?**

+1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

## Dist. by/ por:

Dist. by/ por:

# PHARMADEL LLC

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www.pharmadel.com

# **Principal Display Panel**

NDC 55758-505-01





enzocaine li	quid				
Product In	formation				
Product Typ	e	HUMAN OTC DRUG	ltem Cod	e (Source)	NDC:55758-505
Route of Adı	ninistration	TOPICAL			
Active Ingr	edient/Active	Moiety			
Ingredient Name Basis of Strength					h Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)			18JW5)	BENZOCAINE	200 mg in 1 mL
Inactive In	gredients				
Ingredient Name					Strength
	I: 3K9958V90M)				
	NII: 578389D6D0)				
	II: PDC6A3C0OX)		```		
		PECIFIED (UNII: 3WQ0SDW1A	<b>(</b> )		
	HARIN (UNII: SB82 HYLPARABEN (UNI				
	LYCOL (UNII: 6DC				
Packaging					
# Item Cod	e P	ackage Description		Marketing Start Date	Marketing End Date
1 NDC:55758- 505-01	1 in 1 CARTON		C	05/14/2025	
	15 mL in 1 BO	TTLE, SPRAY; Type 0: Not a			
1	Combination P	roduct			
1	Combination P	roduct			
	Combination P				
1 Marketin Marketin Categor	Combination P		raph	Marketing Start Date	Marketing End Date

Labeler - Pharmadel LLC (030129680)