

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

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**DoloDent (WP)(DA)**

**DRUG FACTS**

**Active ingredient and Purpose**

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<b>Active ingredient</b>	<b>Purpose</b>
Benzocaine 20%.....	Oral pain reliever

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**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** 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](http://www.pharmadel.com)

***Dist. by/ por:***

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**PHARMADEL LLC**

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**+1-866-359-3478**

[www.pharmadel.com](http://www.pharmadel.com)

**Principal Display Panel**

NDC 55758-505-01

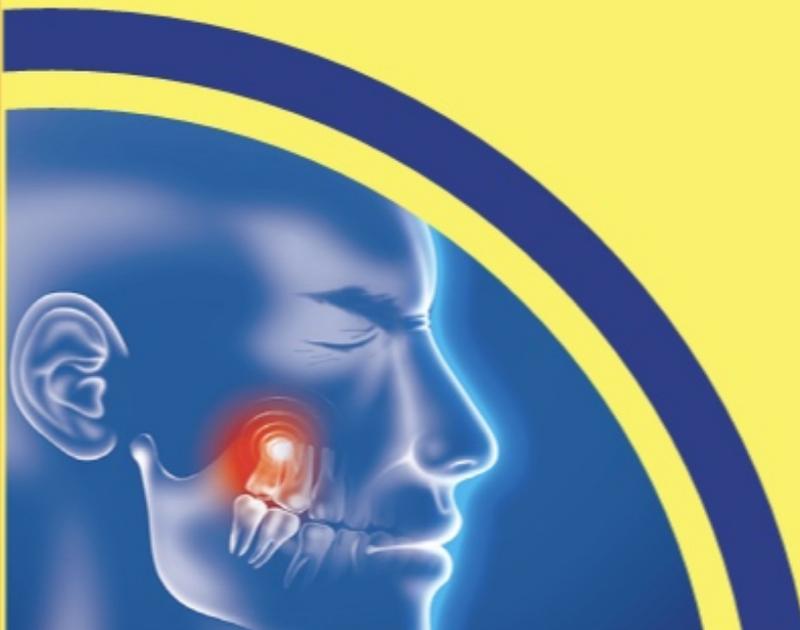
# ***DoloDent***<sup>®</sup>

## ***MAXIMUM STRENGTH***

### ***Spray***

***Instant Oral Pain Relief***  
***Benzocaine 20%***

- Canker Sores
- Sore Gums
- Braces Irritation
- Denture Pain



# DOLODENT MAXIMUM STRENGTH

benzocaine liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-505
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CLOVE OIL</b> (UNII: 578389D6D0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM SACCHARIN</b> (UNII: SB8ZUX40TY)	
<b>SODIUM METHYLPARABEN</b> (UNII: CR6K9C2NHK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-505-01	1 in 1 CARTON	05/14/2025	06/01/2027
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	05/14/2025	06/01/2027

**Labeler** - Pharmadel LLC (030129680)