

**IOLITE-S- benzocaine spray**  
**Dharma Research, Inc.**

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**Active Ingredient**

Benzocaine 20%

**Purpose**

Oral anesthetic

**Uses**

For the temporary relief of occasional minor irritation and pain associated with canker sores and minor dental procedures.

**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 the blood. This can occur even if you have use 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** this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persist or worsens, or if swelling, rash, or fever develops, see your dentist or doctor promptly.

- For teething
- In children under 2 years of age

**Do not use** near fire or flame. Flammable.

**Do not** exceed recommended dosage.

Avoid spraying in the eyes.

**Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.**

## **Directions**

Shake well before use. Firmly insert extension tube into spray can valve and ensure it fits securely in the actuator opening. Position the extension tube 1-2 inches from the affected area. Press 1/2 second (press and immediately release the actuator).

- Adults and children 12 years of age and older: Apply to the affected area. 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 this product.
- Children under 2 years of age: do not use.

## **Inactive Ingredients**

Ethyl alcohol, Flavor, Isobutane (propellant), Polyethylene glycol, Propane (propellant), Saccharine sodium.

## **Other Information**

Store at room temperature 59-86°F (15-30°C).

Manufactured by:

Dharma Research, Inc.

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

5220 N.W. 72 Avenue, Unit 15

Miami, FL 33166

1-877-833-3725

NDC 53045-127-60

Iolite-S


Oral Anesthetic Spray


Gluten Free


Made in USA

2 fl. oz. (60 mL)

Fresh Spearmint

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| <b>Drug Facts</b><br><b>Active Ingredient</b> <b>Purpose</b><br>Benzocaine, 20%.....Oral anesthetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | <b>Drug Facts (continued)</b><br>Do not use near fire or flame. Flammable.<br>Do not exceed recommended dosage<br>Avoid spraying in the eyes.<br><b>Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.</b>                                                                                                                                                                                                                                                   |  |
| <b>Uses</b><br>For the temporary relief of pain associated with canker sores and minor dental procedures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | <b>Directions</b><br>Shake well before use. Firmly insert extension tube into spray can valve and ensure it fits securely in the actuator opening. Position the extension tube 1-2 inches from the affected area. Press 1/2 second (press and immediately release actuator).<br>• Adults and children 12 years of age and older: Apply to the affected area Use up to 4 times daily or as directed by a dentist or doctor.<br>• Children under 12 years of age should be supervised in the use of the product.<br>• Children under 2 years of age: do not use. |  |
| <b>Warnings</b><br><b>Methemoglobinemia warning:</b> Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in 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<br><b>Allergy Alert</b> Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other '-caine' anesthetics.<br><b>Do not use:</b> • This product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persist or worsens, or if swelling, rash or fever develops, see your dentist or doctor promptly;<br>• For teething<br>• In children under 2 years of age |  | <b>Re-order #:</b> 06-00060 <b>Revision D, Date</b> 06/06/2025<br><b>Inactive ingredients</b><br>Ethyl alcohol, Flavor, Isobutane (propellant), Polyethylene glycol, Propane (propellant), Saccharine sodium.<br><b>Other information</b><br>Store at room temperature 59-86° F (15-30° C).<br><br>Manufactured by:<br> <b>DHARMA</b> RESEARCH, INC.<br>WWW.DHARMARESEARCH.COM      5220 N.W. 72 Avenue<br>Unit 15, Miami, FL 33166<br>1-877-833-3725                         |  |

NDC 53045-127-60  
  
**ORAL ANESTHETIC SPRAY**  
**GLUTEN FREE**  
**MADE IN USA**  
2 fl.oz. (60ml)

**FRESH SPEARMINT**  
 **Peel Back Here**

**Packaging**

| # | Item Code        | Package Description                                         | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:53045-127-60 | 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 01/04/2021           |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M022                                     | 01/04/2021           |                    |

**Labeler** - Dharma Research, Inc. (078444642)**Registrant** - Dharma Research, Inc. (078444642)**Establishment**

| Name                  | Address | ID/FEI    | Business Operations    |
|-----------------------|---------|-----------|------------------------|
| Dharma Research, Inc. |         | 078444642 | manufacture(53045-127) |

Revised: 6/2025

Dharma Research, Inc.