**Suggested Formula**

Lidocaine 10%, Prilocaine 10%, Tetracaine 4% Dental Paste (Emulsion, 30 g)

**FIN**  F 006 065v2

### Suggested Formulation

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>NDC #</th>
<th>Supplier</th>
<th>Lot Number</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine, USP</td>
<td>3.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prilocaine, USP</td>
<td>3.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetracaine, USP</td>
<td>1.200</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stevia Powder</td>
<td>0.10</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Butylated Hydroxytoluene (BHT), NF</td>
<td>0.03</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bubble Gum Flavor</td>
<td>0.3</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca OleaBase™ Plasticized</td>
<td>22.37</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Special Preparatory Considerations

**Ingredient-Specific Information**

**Narrow Therapeutic Index**

- **Lidocaine**

**Eutectic Mixture when combined:**

- Lidocaine, Prilocaine, Tetracaine

**Light sensitive (protect from light whenever possible):**

- Tetracaine, Butylated Hydroxytoluene

**Hygroscopic (protect from moisture whenever possible):**

- Stevia Powder

**Moisture sensitive (protect from humidity whenever possible):**

- Butylated Hydroxytoluene

**Heat Sensitive (protect from heat whenever possible):**

- Butylated Hydroxytoluene

**Suggested Preparatory Guidelines**

- □ Non-Sterile Preparation
- □ Sterile Preparation

**Processing Error / Testing Considerations:**

To account for processing error considerations during preparation, it is suggested to measure an additional **12 to 15%** of the required quantities of ingredients.

**Special Instruction:**

Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

**Lidocaine has a Narrow Therapeutic Index.**

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.
SUGGESTED PREPARATION (for 30 g)

Weigh and / or measure the following ingredients when appropriate:

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>Multiplication factor (*)</th>
<th>Processing Error</th>
<th>Qty. to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine, USP</td>
<td>3.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prilocaine, USP</td>
<td>3.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetracaine, USP §</td>
<td>1.200</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stevia Powder §</td>
<td>0.10</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Butylated Hydroxytoluene (BHT), NF §</td>
<td>0.03</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bubble Gum Flavor</td>
<td>0.3</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca OleaBase™ Plasticized</td>
<td>22.37</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Preparatory step:**
   
   A. Prepare a hot water bath.

   **Specifications:** Temperature: 40 to 45°C.
### Suggested Formula

| Lidocaine 10%, Prilocaine 10%, Tetracaine 4% Dental Paste (Emulsion, 30 g) | FIN | F 006 065v2 |

#### 2. Powder-liquid preparation:

**A.** Combine and triturate the following ingredients together:

- Lidocaine
- Prilocaine
- Tetracaine

**Specifications:** Continuously mix. Heat to 40–45°C in the water bath to dissolve if necessary.

**End result:** Homogeneous liquid-like solution.

**B.** In the given order, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 2A):

- Stevia Powder
- Butylated Hydroxytoluene (BHT)
- Bubble Gum Flavor

**Specifications:** Continuously mix.

**End result:** Homogeneous liquid-like dispersion.

#### 3. Medium Integration:

**A.** Incrementally add the homogeneous liquid-like dispersion (Step 2B) to the OleaBase™ Plasticized.

**Specifications:** Continuously mix, using high-shear mixing techniques.

**End result:** Homogeneous paste-like dispersion.

**Note:** If the paste is gritty, pass through an ointment mill until a smooth, homogeneous paste is obtained.

#### 4. Product transfer:

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).
| Suggested Formula | Lidocaine 10%, Prilocaine 10%, Tetracaine 4% Dental Paste (Emulsion, 30 g) | FIN | F 006 065v2 |

**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days, as per USP.</td>
<td>Tightly closed, light-resistant unit dose syringe.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Auxiliary Labels</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Use as directed. Do not exceed prescribed dose.</td>
<td>6 Keep at room temperature (20°C – 23°C).</td>
</tr>
<tr>
<td>2 Keep out of reach of children.</td>
<td>7 For external use only.</td>
</tr>
<tr>
<td>3 Discard the syringe after use.</td>
<td>8 Keep in a dry place.</td>
</tr>
<tr>
<td>4 Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.</td>
<td>9 Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.</td>
</tr>
<tr>
<td>5 May impair mental and/or physical ability. Use care when operating a car or machinery.</td>
<td>10 Protect from light.</td>
</tr>
</tbody>
</table>

**Pharmacist Instructions**

Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.

**IMPORTANT:**
- Small batch is prepared due to inherent potential of systemic toxicity.
  - Limits as to the total amount of product used should be established by a physician.
  - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas.
  - Continued application of this product might produce systemic side effects. Advise patient accordingly.

**IMPORTANT:** DRUG-DRUG INTERACTIONS EXISTS BETWEEN LIDOCAINE AND PRILOCAINE. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.

**Patient Instructions**

Contact your pharmacist in the event of adverse reactions.

**IMPORTANT:**
- The quantity of active ingredient administered is directly dependent on the quantity of product applied.
  - Do not cover the site of application.
Suggested Formula | Lidocaine 10%, Prilocaine 10%, Tetracaine 4% Dental Paste (Emulsion, 30 g) | FIN | F 006 065v2
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REFERENCES


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