Suggested Formula
Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)

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>Baclofen, USP</td>
<td>2.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone (Micronized), USP</td>
<td>0.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flurbiprofen, USP</td>
<td>5.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethoxy Diglycol</td>
<td>4.000</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca Transdermal Pain Base</td>
<td>87.89</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SPECIAL PREPARATORY CONSIDERATIONS

**Ingredient-Specific Information**

- **Light sensitive** (protect from light whenever possible): Dexamethasone
- **Hygroscopic** (protect from moisture whenever possible): Ethoxy Diglycol
- **Heat Sensitive** (protect from heat whenever possible): Dexamethasone

**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 5 to 9% 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.

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 100 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>Baclofen, USP</td>
<td>2.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone (Micronized), USP §</td>
<td>0.500</td>
<td>g</td>
<td></td>
<td></td>
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<tr>
<td>Flurbiprofen, USP</td>
<td>5.000</td>
<td>g</td>
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</tr>
<tr>
<td>Ethoxy Diglycol §</td>
<td>4.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca Transdermal Pain Base</td>
<td>87.89</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. **Powder-liquid preparation:**
   A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:
      - Baclofen
      - Dexamethasone (Micronized)
      - Flurbiprofen
   B. Levigate the fine, homogeneous powder blend (Step 1A) with the Ethoxy Diglycol.

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

2. **Powder-liquid to base incorporation:**
   A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Transdermal Pain Base.

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

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

3. **Product transfer:**
Transfer the final product into the specified dispensing container (see “Packaging Requirements”).
Suggested Formula
Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)

FIN | F 006 055

### 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, metered-dose measuring device.</td>
</tr>
</tbody>
</table>

#### Auxiliary Labels

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use as directed. Do not exceed prescribed dose.</td>
</tr>
<tr>
<td>2</td>
<td>Keep out of reach of children.</td>
</tr>
<tr>
<td>3</td>
<td>For external use only.</td>
</tr>
<tr>
<td>4</td>
<td>Keep at room temperature (20°C – 23°C).</td>
</tr>
<tr>
<td>5</td>
<td>May impair mental and or physical ability. Use care when operating a car or machinery.</td>
</tr>
</tbody>
</table>

#### Pharmacist Instructions

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

**IMPORTANT:** DRUG-DRUG INTERACTION EXISTS BETWEEN DEXAMETHASONE AND FLURBIPROFEN. 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 API administered is directly dependent on the quantity of product applied.

### REFERENCES


Suggested Formula | Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g) | FIN | F 006 055
---|---|---|---

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