Suggested Formula
Gabapentin 10% Topical Gel (Suspension, 15 g) FIN F 006 611

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>Gabapentin, USP</td>
<td>1.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol, USP</td>
<td>1.1</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca CopaSil™</td>
<td>12.36</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): Gabapentin, Propylene Glycol, CopaSil™
- **Hygroscopic** (protect from moisture whenever possible): Propylene Glycol

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 15 to 20% 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 15 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>Gabapentin, USP §</td>
<td>1.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol, USP §</td>
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<td>Medisca CopaSil™ §</td>
<td>12.36</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

§ Weigh / measure just prior to use.

* Takes into account increased batch size conversions and density conversions, if required.

### Preparatory Instruction

1. **Powder-liquid preparation:**
   
   A. Triturate the Gabapentin to form a fine, homogeneous powder.
   
   B. Levigate the fine homogeneous powder (Step 1A) with the Propylene Glycol.

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

2. **Powder-liquid to medium integration:**
   
   A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the CopaSil™.

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

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

   B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.

3. **Product transfer:**
   
   Transfer the final product into the specified dispensing container (see “Packaging Requirements”).
**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months, as per USP*</td>
<td>- Tightly closed, light-resistant container.</td>
</tr>
<tr>
<td></td>
<td>- To be administered with a metered-dose measuring device.</td>
</tr>
</tbody>
</table>

**Auxiliary Labels**

1. Use as directed. Do not exceed prescribed dose.
2. Keep out of reach of children.
3. Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
4. May impair mental and/or physical ability. Use care when operating a car or machinery.
5. For external use only.

**Pharmacist Instructions**

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

**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.

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

**REFERENCES**

| Suggested Formula | Gabapentin 10% Topical Gel (Suspension, 15 g) | FIN | F 006 611 |


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