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>Progesterone (Micronized), USP</td>
<td>1.667</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol, USP</td>
<td>0.8</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca HRT Cream Base</td>
<td>7.79</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SPECIAL PREPARATORY CONSIDERATIONS

- **Light Sensitive** (protect from light whenever possible): Progesterone, Propylene Glycol
- **Hygroscopic** (protect from moisture whenever possible): Propylene Glycol

**Ingredient-Specific Information**

- **Non-Sterile Preparation**
- **Sterile Preparation**

**Processing Error / Testing Considerations:**

To account for processing error considerations during preparation, it is suggested to measure an additional 20 to 25% of the required quantities of ingredients.

**Special Instruction:**

This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed official implementation date of December 31st, 2019.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP 795 and USP 800, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIIs) and Compliance Policy Guides (CPGs).

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 10 mL)**

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>Progesterone (Micronized), USP §</td>
<td>1.667</td>
<td>g</td>
<td></td>
<td></td>
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<tr>
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<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. Levigate the Progesterone (Micronized) 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 1A) to the HRT Cream Base.

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

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

3. **Product transfer:**
   A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).
<table>
<thead>
<tr>
<th>Suggested Formula</th>
<th>Progesterone 25mg/0.15mL Topical Cream (Emulsion, 10 mL)</th>
</tr>
</thead>
</table>

**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>30 days, as per USP.</th>
<th>Packaging Requirements</th>
<th>- To be administered in a tightly closed, light-resistant metered-dose MD Mini Pump measuring device.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use as directed. Do not exceed prescribed dose.</td>
<td>6</td>
<td>Cap tightly after use.</td>
</tr>
<tr>
<td>2</td>
<td>Keep out of reach of children.</td>
<td>7</td>
<td>Keep at room temperature (20°C – 23°C).</td>
</tr>
<tr>
<td>Aux Labels</td>
<td>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.</td>
<td>8</td>
<td>Keep in a dry place.</td>
</tr>
<tr>
<td></td>
<td>4 Protect from light.</td>
<td>9</td>
<td>Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.</td>
</tr>
<tr>
<td></td>
<td>5 May impair mental and/or physical ability. Use care when operating a car or machinery.</td>
<td>10</td>
<td>For external use only.</td>
</tr>
</tbody>
</table>

**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.
Suggested Formula | Progesterone 25mg/0.15mL Topical Cream (Emulsion, 10 mL) | FIN | F 007 841

**REFERENCES**


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