**FIRST**- Progesterone VGS

**Progesterone Vaginal Suppository USP Compounding Kit**

**FOR PRESCRIPTION COMPOUNDING ONLY**

**DESCRIPTION**

Each **FIRST**- Progesterone VGS Compounding Kit is comprised of micronized progesterone powder and fatty acid base (hard fat NF).* The progesterone contained in this product is derived from soy. **FIRST**- Progesterone VGS Compounding Kits also contain the following components necessary to prepare 30 suppositories: 30-unit suppository mold w/caps, stirrer, suppository filling tool, guide plate, and 30-unit suppository mold protective cover w/suppository dispensing tool attached.

**How Supplied and Compounding Directions**

**When compounding:**
- Use personal protective equipment as required.
- Avoid inhalation and contact with skin, eyes, and clothing.
- Use personal protective equipment as required.
- Avoid interruption while compounding to limit exposure.

**SIZE**

<table>
<thead>
<tr>
<th>Size</th>
<th>100 mg</th>
<th>200 mg</th>
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</thead>
<tbody>
<tr>
<td>NDC#</td>
<td>65628-062-01</td>
<td>65628-063-01</td>
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<tr>
<td>Progesterone USP</td>
<td>3.0 g</td>
<td>6.0 g</td>
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<tr>
<td>Fatty Acid Base (Hard Fat NF)</td>
<td>66.0 g</td>
<td>63.0 g</td>
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**TO THE PHARMACIST**

Prior to compounding, store **FIRST**- Progesterone VGS Compounding Kits at room temperature between 15°-30°C (59°-86°F) [see USP]. Store the compounded suppositories in the 30-unit suppository mold in the refrigerator (2°-6°C [36°-46°F]). The preparation of vaginal suppositories using **FIRST**- Progesterone VGS Compounding Kit complies with the requirements of USP, and as such, compounded suppositories made using **FIRST**- Progesterone VGS Compounding Kit can be used for up to ninety days after the day on which they were compounded.

When compounded and dispensed according to the instructions, average contraceptive weight has been found to be 2.3 grams and contain 90-110% of progesterone as labeled.**

The suppository mold and its accessories contained in this kit meet the requirements for USP Cytotoxicity Test, as well as Class VI Tests for plastic containers.**

The suppository mold and its accessories contained in this kit meet the requirements for USP Cytotoxicity Test, as well as Class VI Tests for plastic containers.**

**Instructions:**

1. **FIRST**- Progesterone VGS Compounding Kits contain preweighed progesterone powder and preweighed fatty acid base in sufficient quantity for the pharmacist to prepare 30 vaginal suppositories.

   *Important:* Prior to compounding and dispensing, read the instructions completely and make certain that all the components are present. Place all components and use in each step.

2. Remove the cap from the jar containing fatty acid base and melt the base placing the jar in a standard microwave. Melt times may vary depending on the type of microwave used. It is recommended that you initially set the timer for 1 minute and check to see if the base has melted. If it has not, return the jar of base to the microwave for 15 second increments until the base is completely melted. Generally, the fatty acid base will completely melt between 1 and 3 minutes. **DO NOT OVERHEAT.**

3. With your fingers, tap the top and bottom of the bottle to loosen the progesterone powder and remove the cap. Empty the contents of the bottle into the jar containing the melted fatty acid base. It is recommended that you also tap the bottom and sides of the bottle while emptying. Recap bottle securely. Place the provided guide plate attached to the mold cover on top of the suppository mold. This will ensure that the 30 suppository cavities are aligned with the raised holes in the guide plate. Gently push the guide plate down to lock it in place. It is important that you fit the guide plate properly in order for your patient to dispense the suppositories easily.

   **IMPORTANT:**

   Make certain the notches and alignment key on the guide plate align with notches and alignment key on suppository mold.

   This will ensure that the 30 suppository cavities are aligned with the raised holes in the guide plate. For vaginal use only.

   • Do not take orally
   • Do not insert in urinary opening or anus
   • Avoid contact with eyes
   • Keep out of reach of children
   • Protect from light
   • Keep container tightly closed
   • Store suppository in the refrigerator, in the refrigerator
   • Remove used caps from suppositories prior to use

   * Certificate of analysis on file
   * * Data and documentation on file

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**Manufactured for:**

Wilmington, MA 01878 USA

www.azurity.com