TO THE PHARMACIST

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

1. FIRST® - Progesterone VGS 100 Compounding Kit contains pre-weighed progesterone powder and pre-weighed fatty acid base in sufficient quantity for the pharmacist to prepare 30 vaginal suppositories, each containing 100 mg of progesterone. Important - Prior to compounding and dispensing, read the instructions completely and make certain that all the components are present. Place all components aside until instructed to use in each step.

2. Remove the cap from jar containing fatty acid base and melt the base placing the jar in a standard microwave. Melting 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 finger, 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 when finished emptying. The appropriate quantity of progesterone powder has been packaged in the bottle to deliver enough progesterone to provide 100 mg for each suppository.
Prior to compounding, store FIRST® Progesterone VGS 100 Compounding Kit at room temperature between 15º-30ºC (59º-86ºF) [see USP]. Also, store the compounded suppositories in the 30-unit suppository mold in the refrigerator (2º-8ºC [36º-46ºF]). FIRST® Progesterone VGS 100 Compounding Kit components have a two-year expiration date.** The preparation of vaginal suppositories using FIRST® Progesterone VGS 100 Compounding Kit complies with the requirements of USP, and as such, compounded suppositories made using FIRST® Progesterone VGS 100 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 suppository 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.**

Instruct patient as follows:
• 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 suppositories in the mold, in the refrigerator
• Remove red caps from suppositories prior to use

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

Dispose of waste in accordance with all applicable state/federal laws and regulations.

Prior to compounding, store FIRST® Progesterone VGS 100 Compounding Kit at room temperature between 15º-30ºC (59º-86ºF) [see USP]. Also, store the compounded suppositories in the 30-unit suppository mold in the refrigerator (2º-8ºC [36º-46ºF]). FIRST® Progesterone VGS 100 Compounding Kit components have a two-year expiration date.** The preparation of vaginal suppositories using FIRST® Progesterone VGS 100 Compounding Kit complies with the requirements of USP, and as such, compounded suppositories made using FIRST® Progesterone VGS 100 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 suppository 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.**

Instruct patient as follows:
• 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 suppositories in the mold, in the refrigerator
• Remove red caps from suppositories prior to use

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

R only

Revised: May 2015

U.S. Patents: 7,434,690 B2; 7,815,929 B2; 8,276,757 B2

Manufactured for:

CutisPharma® Inc.
Transforming Compounding through Innovation™
Wilmington, MA 01887, USA www.cutispharma.com