

Progesterone 55 mg/g (5.5%) Cream (Phytobase®)(BUD Study)

Total Formula Quantity

100 grams

Ingredients

Quantity

Progesterone USP Micronized	5.5 grams	
Diethylene Glycol Monoethyl Ether NF	5.5 grams	5.55 milliliters
Phytobase™	89 grams	

Ingredient Disclaimer

The density of Diethylene Glycol Monoethyl Ether is 0.991 g/mL

This formulation contains ingredient(s) that are on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. Follow all relevant USP <800> guidelines when handling, storing, and compounding with this material.

Method/Instructions

1. Calculate amount of ingredients needed.
2. Accurately weigh and measure each ingredient.
3. Wet Progesterone with Diethylene Glycol Monoethyl Ether.
4. Combine with Phytobase and mix on FagronLab EMP until homogenous.
5. Run through ointment mill and mix again as desired.
6. Package in Topi-Click container.

 Formulation Notes

- For optimal results this formulation should be compounded using mechanical mixing devices that ensure thorough mixing and produce high shearing forces (electronic mortar & pestle combined with processing through an ointment mill).

 Equipment

FagronLab EMP

 Supplies/Dispensers

Topi-Click

 PPE Notes

Refer to USP <800> current guidelines for specific minimum garbing requirements. Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Refer to current USP <800> and USP <795> or USP <797> guidelines as well as the facility's SOPs for additional information on personal protective equipment (PPE) for non-sterile and sterile hazardous compounding.

Refer to USP <795> current guidelines for specific minimum garbing requirements. Gloves must be worn for all compounding activities. Additional garb may be necessary depending on the type of compounding performed and per the facility's SOP.

 Storage

Controlled Room Temperature 20 to 25 °C

Store in a tightly closed container

Protect from light

 BUD

180 days per study

AUX

This medication was specially compounded in our pharmacy for you at the direction of your prescriber.

References

- Taylor S, Haselhorst R. Extended chemical and microbial stability of various hormones in Phytobase and HRT Heavy Cream Bases. Int J Pharm Compd. 2024; 28(4): 344-350.
- The ESTIMATED BEYOND-USE DATE is a physical stability estimate based on information from published references, medical and scientific literature, observed organoleptic stability, formulator practical experience and current USP guidelines. Please refer to USP Chapter <795> for additional information regarding appropriate Beyond-Use determination.

QC check section

Describe the appearance of the finished compound (color, odor, etc):

Compounded Active Pharmaceutical Ingredients match the original prescription document: Yes / No

Describe the closure container used for finished compound (Topiclick, etc.):

Quality control measures taken and results (pH measurements ,etc):

Visual inspection of compound within expectations: Yes / No

Container closure checked for and free of any leakage and/or cracks: Yes / No

Compounded preparation released for dispensing by (name):

 Disclaimer

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