

FIRST® - Testosterone MC [Ⓜ]Ⓡ

2% Testosterone MC in Moisturizing Cream Base Compounding Kit

FOR PRESCRIPTION COMPOUNDING ONLY

DESCRIPTION

Each FIRST® - Testosterone MC in Moisturizing Cream Base Compounding Kit contains 1.4312 grams of micronized testosterone propionate USP (100 mg testosterone per mL) in solution* (total volume: 12 mL) with sesame oil NF, butylated hydroxytoluene NF, and benzyl alcohol NF.

FIRST® - Testosterone MC in Moisturizing Cream Base Compounding Kit also contains 48 grams of Moisturizing Cream Base for topical use. When compounded, the final product provides an homogeneous formulation containing 2% testosterone.

How Supplied and Compounding Directions

Size (Net Weight)	60 grams
NDC#	65628-021-01
Testosterone Solution	12 mL (100 mg/mL)
Moisturizing Cream Base	48 grams

One 5 mL teaspoonful is approximately equivalent to 6.1 gm of compounded product containing equivalent of 122 mg of testosterone.

TO THE PHARMACIST

Everything you need to make this [Ⓜ] is included...



1. FIRST® - Testosterone MC in Moisturizing Cream Base Compounding Kit contains pre-weighed moisturizing cream base in a mixing jar, pre-measured testosterone solution, and a stirrer.



2. Important - Be careful not to spill the contents while mixing. Prior to dispensing, pour a few drops of the testosterone propionate in oil into moisturizing cream base.



3. Mix well to wet the base.



4. Continue to gradually add testosterone propionate in oil into moisturizing cream base and mix until all of the testosterone propionate in oil has been added to the moisturizing cream base



5 Continue stirring until homogeneous in appearance (2 to 3 minutes).

Prior to compounding, store FIRST® - Testosterone MC in Moisturizing Cream Base Compounding Kit at room temperature between 15°-30°C (59°-86°F). Also store final formulation at room temperature, 15°-30°C (59°-86°F).

FIRST® - Testosterone MC in Moisturizing Cream Base Compounding Kit components have a three-year expiration date.** Based on real time controlled room temperature and humidity testing, compounded FIRST® - Testosterone MC in Moisturizing Cream Base is stable for at least six months.**

Each lot of FIRST® - Testosterone MC solution meets USP Microbial Limit Tests <61>** for the absence of USP designated pathogens, as well as not more than 100 CFU/mL for total bacterial count and for total yeast and mold. FIRST® - Testosterone MC solution also meets USP Antimicrobial Effectiveness Testing <51>**.

Antimicrobial effectiveness has been demonstrated in freshly prepared testosterone propionate solution samples and testosterone propionate solution samples stored at accelerated ICH storage conditions (40±2°C/75%RH).

For external use only. Avoid contact with eyes. Keep container tightly closed. Keep out of the reach of children. Compounded product, as dispensed, is **stable for at least 180 days** at room temperature.

* Certificate of analysis on file

** Data and documentation on file

[Ⓜ] ONLY

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Additional U.S. Patent Pending

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