

# FIRST® - Testosterone

## 2% Testosterone in White Petrolatum Compounding Kit

**FOR PRESCRIPTION COMPOUNDING ONLY**

### DESCRIPTION

Each FIRST®- Testosterone in White Petrolatum 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 in White Petrolatum Compounding Kit also contains 48 grams of white petrolatum 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#	65628-020-01
Testosterone Solution	12 mL (100 mg/mL)
White Petrolatum	48 grams

One 5 mL teaspoonful is approximately equivalent to 5.3 gm of compounded product containing equivalent of 106 mg of testosterone.

### TO THE PHARMACIST

*Everything you need to make this  $\mathcal{R}$  is included...*



1. FIRST®- Testosterone in White Petrolatum Compounding Kit contains pre-weighed white petrolatum in a mixing jar, pre-measured testosterone solution, and a stirrer.



2. **Important** - Prior to dispensing, pour the entire contents of the bottle containing testosterone propionate in oil into white petrolatum.



3. Stir gently until homogeneous in appearance (2 to 3 minutes).

Prior to compounding, store FIR&ST®- Testosterone in White Petrolatum 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).

FIR&ST®- Testosterone in White Petrolatum Compounding Kit components have a three-year expiration date.\*\* Based on real time controlled room temperature and humidity testing, *compounded* FIR&ST®- Testosterone in White Petrolatum is stable for at least six months.\*\*

Each lot of FIR&ST®- Testosterone 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. FIR&ST®- Testosterone 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

## R ONLY

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Additional U.S. Patent Pending

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