

# FIRST<sup>®</sup> - Hydrocortisone R

## 10% Hydrocortisone in Ultrasound Gel Compounding Kit

**FOR PRESCRIPTION COMPOUNDING ONLY**

### DESCRIPTION

Each FIRST<sup>®</sup> - Hydrocortisone in Ultrasound Gel Compounding Kit contains 6 grams of micronized hydrocortisone USP in a suspension\* (total weight: 24 g) with propylene glycol USP and simethicone USP.

FIRST<sup>®</sup> - Hydrocortisone in Ultrasound Gel Compounding Kit also contains 36 grams of ultrasound gel for topical use. When compounded, the final product provides an homogeneous gel/cream containing 10% hydrocortisone.

### How Supplied and Compounding Directions

|                           |              |
|---------------------------|--------------|
| Size (Net Weight)         | 60 grams     |
| NDC#                      | 65628-010-01 |
| Hydrocortisone Suspension | 24 grams     |
| Ultrasound Gel            | 36 grams     |

### TO THE PHARMACIST

*Everything you need to make this R is included...*



1. FIRST<sup>®</sup> - Hydrocortisone in Ultrasound Gel Compounding Kit contains pre-weighed hydrocortisone suspension in a mixture of propylene glycol and simethicone in a mixing jar, pre-weighed ultrasound gel, and a stirrer.



2. Prior to dispensing, carefully peel back the inner foil seal of the jar containing the hydrocortisone suspension. Incorporate all of the hydrocortisone suspension, including any material on the inner seal.



3. **Important** - Empty the ultrasound gel into the hydrocortisone suspension by thoroughly squeezing the entire pouch.



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

Prior to compounding, store FIR<sub>ST</sub><sup>®</sup> - Hydrocortisone in Ultrasound Gel 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<sub>ST</sub><sup>®</sup> - Hydrocortisone in Ultrasound Gel Compounding Kit components have a two-year expiration date.\*\* Based on real time controlled room temperature and humidity testing, *compounded* FIR<sub>ST</sub><sup>®</sup> - Hydrocortisone in Ultrasound Gel is stable for at least six months.\*\*

Each lot of FIR<sub>ST</sub><sup>®</sup> - Hydrocortisone suspension meets the requirements for total aerobic microbial count of not more than 100 cfu/mL, as well as for the absence of the specified microorganisms *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella spp.* when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. FIR<sub>ST</sub><sup>®</sup> - Hydrocortisone suspension also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 2 products.

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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