



### SUGGESTED FORMULA

---

#### Gentamicin Sulfate 1mg/mL, Clotrimazole 0.25 mg/mL Nasal Spray

Version number: 1.0

Volume: 100 mL

---

Gentamicin Sulfate, USP	0.1 g*
Clotrimazole, USP (CL127)	0.025 g
Alcohol, 190 Proof, USP (ET108)	10 mL
Propylene Glycol, USP (PR130)	20 mL
Benzalkonium Chloride, NF 50% (B1068)	15 mg**
Water, sterile for injection or irrigation	QS 100 mL

---

\*Adjust amount to be weight per assay reported in certificate of analysis.

\*\*The benzalkonium chloride can be obtained by diluting 1 mL of benzalkonium chloride 50% solution to 100 mL which results in a concentration of 5 mg/mL. Three mL of this dilution can be used for this formula.

#### SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient.
3. Dissolve the clotrimazole in the alcohol.
4. Add the propylene glycol and mix well.
5. Add the benzalkonium chloride solution (3 mL at 5mg/mL).
6. Add enough water to bring the solution to 50% of final volume.
7. Add gentamicin sulfate and mix well.
8. Add sufficient sterile water for injection to volume and mix well placing in a nasal delivery bottle.
9. Package and label.
10. Quality Assessments:
  - a. Weight to Volume calculation
  - b. Proper packaging
  - c. Color

Store in air tight containers

Store at room temperature.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

**Beyond-Use Date should be assigned as directed by the current USP <795>**

**Precautions:**

General precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.

1/18 RD