



SUGGESTED FORMULA

Ketoconazole 2% Antifungal Nail Solution

Version number: 1.0

Volume: 90mL

Ketoconazole, USP (K1149)	1.8gm
Alcohol 95%, USP (ET108)	5mL
Polyethylene Glycol 300, NF (PO108)	67mL
Dimethyl Sulfoxide, USP (DMSO) (D1258)	23mL

SUGGESTED COMPOUNDING PROCEDURES

1. Accurately weigh and/or measure each ingredient
2. Triturate the Ketoconazole if clumps are present
3. In a calibrated vessel (with spin bar) add Ketoconazole and alcohol to soften
4. Add Polyethylene Glycol 300, mix and heat gently while stirring constantly for at least an hour
5. Add DMSO and filter
6. Package in nail polish bottles and label
7. Suggested quality assessments:
 - a. Clarity
 - b. Color
 - c. Label (s) - auxiliary labels (external use), storage, BUD

Apply very sparingly to affected area

Keep away from eyes and mucous membranes

External Use Only

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 according to the current USP Chapter <795>

Precautions:

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.

6/19 JD