



SUGGESTED FORMULA

Amitriptyline Hydrochloride 2% (20 mg/g) Cream

Version number: 1.0

Volume or quantity: 30 g

Amitriptyline Hydrochloride, USP (A1322)	0.6 g
2-(2-Ethoxyethoxy) ethanol (E1022)	1 mL
Durabase Advanced (B4512)	Q.S. 30 g

*Amitriptyline Hydrochloride as a salt may cause separation in emulsion-type bases. Compounders may add Sepineo P600™ (S2019) at a concentration of between 0.5% and 5% to increase viscosity and prevent emulsion separation.

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SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required amount for each ingredient
2. Weigh and/or measure each ingredient
3. Transfer Amitriptyline Hydrochloride to mortar and triturate to fine powder
4. Add 2-(2-Ethoxyethoxy) ethanol and mix to form paste
5. Geometrically combine step 4 into cream base and mix thoroughly
6. Bring step 5 to final weight and mix thoroughly
7. Package and label
8. Suggested Quality assessments:
 - a. color
 - b. texture, no grit
 - c. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, at controlled 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 from 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 based on the current USP <795> Standards

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.

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