



SUGGESTED FORMULA

Amitriptyline HCL 100mg/mL Transdermal

Version number: 1.0

Volume or quantity: 6 mL

Amitriptyline Hydrochloride, USP (A1322)	0.6 g
Durabase Cream (B4514)	Q.S. 6mL

SUGGESTED COMPOUNDING PROCEDURES

There are numerous methods for compounding transdermals – this is one method:

1. Weigh Amitriptyline Hydrochloride in weigh boat.
2. Fill 10ml syringe (or appropriate size per batch size) with Durabase Cream to 6ml. This is syringe #1.
3. Express 2mL (or 1/3 of syringe volume) from syringe #1 into the weigh boat and mix in the Amitriptyline HCL with a spatula.
4. Remove the plunger from a second syringe and transfer step 3 from the weigh boat to the syringe barrel, insert the plunger and measure the volume. This is syringe #2.
5. From syringe #1 discard an amount Durabase Cream so the two syringes together equal the final volume (6mL).
6. Attach a Luer-lock to Luer-Lock connector to both syringes and mix the contents back and forth between the syringes 15 to 20 times, until uniform.
7. Transfer to dispensing syringes with Luer-Lock to Oral Slip connector or to click-pen and label.
8. Suggested Quality assessments:
 - a. color
 - b. texture, no grit
 - c. no air bubbles
 - c. container
 - d. 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 estimated 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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