



### SUGGESTED FORMULA

Azelaic Acid 4% Cream

Version number: 1.0

Volume or quantity: 100 gm

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Azelaic Acid	4gm
Butylated Hydroxytoluene, NF (B1196)	0.4gm
Polysorbate 80, NF (PO138)	3mL
Propylene Glycol, USP (PR130)	2.5mL
Sodium Metabisulfite, NF (SO182)	0.3gm
Lipocream (B4520)	QS 100gm

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### SUGGESTED COMPOUNDING PROCEDURES

1. Measure and/or weigh all ingredients
2. Transfer Butylated Hydroxytoluene to mortar and triturate crystals to fine powder
3. Add Azelaic Acid to mortar and triturate into step 2
4. Add enough Propylene Glycol to form paste, then add remaining Propylene Glycol
5. Add Polysorbate 80 and mix well
6. Using geometric dilution add Lipocream Base and mix well
7. Process step 6 through ointment mill and/or electronic mortar and pestle to reduce grit
8. Package and label
9. Suggested Quality assessments:
  - a. color
  - b. texture
  - c. container
  - d. Label - auxiliary labels, storage, BUD, compounded medication

Store in light resistant 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 based on the current guidelines of USP Chapter <795>**

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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Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: [SpectrumRx.com](http://SpectrumRx.com) | Email: [sales@spectrumrx.com](mailto:sales@spectrumrx.com)  
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