

Azelaic Acid 15% Cream (Versatile™ Anhydrous Cream)

Total Formula Quantity

100 grams

Ingredients

Quantity


Azelaic Acid	15 grams	
Diethylene Glycol Monoethyl Ether NF	8 grams	8.07 milliliters
Versatile™ Anhydrous Cream	77 grams	

Ingredient Disclaimer


The density of Diethylene Glycol Monoethyl Ether is 0.991 g/mL

Method/Instructions

1. Calculate amount of ingredients needed.
2. Accurately weigh and measure each ingredient.
3. Add all ingredients to mixing jar and mix for 5 minutes at a medium mixing speed using the FagronLab EMP or Pro.
4. If needed, process through a 3 roll ointment mill and remix on EMP for 1 minute at a low mixing speed.
5. Allow the cream to rest for 10 minutes, then package in dispensing container.

 **Formulation Notes**

- For optimal results this formulation should be compounded using mechanical mixing devices that ensure thorough mixing and produce high shearing forces (electronic mortar & pestle combined with processing through an ointment mill).
- If final compounded product is thin after mixing, allow product to rest for 15 minutes to thicken then remix at low speed for 1 minute to ensure consistency.

 **Equipment**

FagronLab EMP

 **Supplies/Dispensers**

Topi-Click

Topi-Pump

ExactDose Adapter

 **PPE Notes**

Refer to USP <795> current guidelines for specific minimum garbing requirements. Gloves must be worn for all compounding activities. Additional garb may be necessary depending on the type of compounding performed and per the facility's SOP.

 **Storage**

Controlled Room Temperature 20 to 25 °C

Protect from light

Store in a tightly closed container

 **BUD**


Dating per USP <795>

- Non-preserved aqueous = 14 days
- Preserved aqueous = 35 days
- Nonaqueous oral liquids = 90 days
- Other nonaqueous dosage forms = 180 days


 AUX

This medication was specially compounded in our pharmacy for you at the direction of your prescriber.

For Topical Use Only

 References

The ESTIMATED BEYOND-USE DATE is a physical stability estimate based on information from published references, medical and scientific literature, observed organoleptic stability, formulator practical experience and current USP guidelines. Please refer to USP Chapter <795> for additional information regarding appropriate Beyond-Use determination.

 QC check section

Describe the appearance of the finished compound (color, odor, etc):

Compounded Active Pharmaceutical Ingredients match the original prescription document: Yes / No

Describe the closure container used for finished compound (Topiclick, etc.):

Quality control measures taken and results (pH measurements ,etc):

Visual inspection of compound within expectations: Yes / No

Container closure checked for and free of any leakage and/or cracks: Yes / No

Compounded preparation released for dispensing by (name):

 A red circle with a white exclamation mark inside.
Disclaimer

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Date last modified

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