



Suggested Formula	Minoxidil 3%, Tretinoin 0.025% Topical Foam (Solution, 50 mL)	FIN	F 006 823v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Minoxidil, USP	1.500	g				
Tretinoin 1% Stock Solution †	1.25	mL				
Butylated Hydroxytoluene (BHT), NF	0.05	g				
Medisca Foamil™ Base	q.s. to 50.0	mL				
† <b>Tretinoin 1% Stock Solution</b>						
Tretinoin (Retinoic Acid), USP	0.100	g				
Ethoxy Diglycol	9.0	mL				
Ethoxy Diglycol	q.s. to 10.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible):

*Minoxidil, Tretinoin, Butylated Hydroxytoluene, Foamil™ Base*

**Narrow Therapeutic Index:**

*Minoxidil*

**Heat Sensitive** (protect from heat whenever possible):

*Tretinoin, Butylated Hydroxytoluene*

**Hygroscopic** (protect from moisture whenever possible):

*Ethoxy Diglycol*

**Oxygen sensitive** (protect from air whenever possible):

*Tretinoin*

**Moisture sensitive** (protect from humidity whenever possible):

*Butylated Hydroxytoluene*

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error /

Testing Considerations:

To account for processing error considerations during preparation, it is suggested to measure an additional **10 to 12%** of the required quantities of ingredients.

Special Instruction:

Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

**Minoxidil has a narrow therapeutic index.**

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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**SUGGESTED PREPARATION (for 50 mL)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Minoxidil, USP §	1.500	g			
Tretinoin 1% Stock Solution † §	1.25	mL			
Butylated Hydroxytoluene (BHT), NF §	0.05	g			
Medisca Foamil™ Base §	q.s. to 50.0	mL			
<b>† Tretinoin 1% Stock Solution</b>					
Tretinoin (Retinoic Acid), USP §	0.100	g	---	---	
Ethoxy Diglycol §	9.0	mL	---	---	
Ethoxy Diglycol §	q.s. to 10.0	mL	---	---	

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.

**Preparatory Instruction**

1. **† Tretinoin 1% Stock Solution preparation:**
  - A. Triturate the Tretinoin (Retinoic Acid) (0.100 g) to form a fine, homogeneous powder.
  - B. Incrementally add the fine, homogeneous powder (Step 1A) to the Ethoxy Diglycol (9.0 mL).  
Specifications: Continuously mix until all solid particles have completely dissolved.  
End result: Homogeneous liquid-like solution.
  - C. Add additional Ethoxy Diglycol to the mixture (Step 1B) to fill to the required batch size (10.0 mL).  
Specifications: Continuously mix.  
End result: Homogeneous liquid-like solution.



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2.	<p><b><u>Powder-liquid to medium integration:</u></b></p> <p>A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"><li>-Minoxidil</li><li>-Butylated Hydroxytoluene (BHT)</li></ul> <p>B. Levigate the fine, homogeneous powder blend (Step 2A) with the Tretinoin 1% Stock Solution (1.25 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogenous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Foamil™ Base to the homogeneous liquid-like dispersion (Step 2B) to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until all solid particles have been dispersed.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
4.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p>



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	30 days, as per USP.	Packaging Requirements	- Tightly closed, light-resistant topical dispensing bottle. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	May impair mental and/or physical ability. Use care when operating a car or machinery.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	Keep out of reach of children.	8	Protect from light.
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	For external use only.
	5	Keep at room temperature (20°C – 23°C).		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions. <b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.			



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## REFERENCES

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4.	Minoxidil (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6285.
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6.	Minoxidil. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 334.
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