MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net

Suggested Formula	Minoxidil 6.0 % to 15.0 % Topical Foam (Solution, 100 mL)	FIN	F 008 224

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Minoxidil, USP	TBD					
Lactic Acid (Racemic) (88%), USP	4.00	g				
Medisca Foamil™ Base	70.0	mL				
Medisca Foamil™ Base	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Minoxidil, Foamil™ Base*

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

Narrow Therapeutic Index: *Minoxidil*

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 **5 to 9%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Minoxidil, USP §	TBD				
Lactic Acid (Racemic) (88%), USP §	4.00	g			
Medisca Foamil™ Base §	70.0	mL			
Medisca Foamil™ Base §	q.s. to 100.0	mL			

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Ingredient quantification:**

A. Based on the desired strength of the Topical Foam, determine the required quantity of Minoxidil to weigh for a 100 mL batch, for example:

Required concentration of Minoxidil	Minoxidil quantity to weigh for 100 mL Batch Size		Processing Error adjustments		Minoxidil to weigh (*plus* processing error adjustments)
6.0%	6.000 g	Multiply	1.05 to 1.09	Equals	_____ g
15.0%	15.000 g				_____ g

2. **Powder-liquid preparation:**

A. Triturate the Minoxidil (amount determined in Step 1A) to form a fine, homogeneous powder.

B. In the given order, sequentially add the following ingredients in the Foamil™ Base (70.0 mL *plus* processing error adjustments):

-Lactic Acid (Racemic) (88%)
-Fine, homogeneous powder (Step 2A)

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

Note: Add the next ingredient, once the previous one has been completely added and dissolved.

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3.	**Filling to volume:** A. Add additional Foamil™ Base to the homogeneous liquid-like solution (Step 2B) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
4.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	180 days at 25°C ± 2°C, based on available stability studies through Medisca*		Packaging Requirements	Tightly closed, light-resistant MD Foamer dispensing bottles.
	*This formula was studied as a bracketed concentration range of Minoxidil 6.0 % to 15.0 %. Any concentration compounded at or between these strengths may apply the suggested BUD based on the **exact** execution of the indicated ingredient list, procedures and quantities listed within this formulation. ***Note:*** ***This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.***			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	Keep out of reach of children.	7	Protect from light.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Keep at controlled room temperature (20°C – 25°C).
	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	Keep in a dry place.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		
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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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REFERENCES

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2. Minoxidil. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1342.
3. Minoxidil (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6285.
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6. USP <795>. *United States Pharmacopeia XLI / National Formulary 36.* Rockville, MD. US Pharmacopeial Convention, Inc. 2018: 6546.