



Suggested Formula	Fluconazole 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 818v2
-------------------	---	-----	-------------

### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fluconazole, USP	2.000	g				
Ethoxy Diglycol	3.0	mL				
Medisca ADA™ Shampoo Base	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

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

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

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



Suggested Formula	Fluconazole 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 818v2
-------------------	---	-----	-------------

**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
Fluconazole, USP §	2.000	g			
Ethoxy Diglycol §	3.0	mL			
Medisca ADA™ Shampoo Base	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.

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

**Preparatory Instruction**

1.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Triturate the Fluconazole to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 1A) with the Ethoxy Diglycol.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
2.	<p><b><u>Powder-liquid to medium integration:</u></b></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the ADA™ Shampoo Base.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Purified Water to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
4.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process in order to maintain homogeneity.</p>



Suggested Formula	Fluconazole 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 818v2
-------------------	---	-----	-------------

**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	Keep out of reach of children.	7	Protect from light.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	For external use only.
	4	Keep at room temperature (20°C – 23°C).	9	<b>Shake well before use.</b>
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	10	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. <b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.			



Suggested Formula	Fluconazole 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 818v2
-------------------	---	-----	-------------

## REFERENCES

1.	Cosmetics for special populations and for use as vehicles. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 441.
2.	Fluconazole. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 532.
3.	Fluconazole (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #4153.
4.	Fluconazole. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 207.
5.	Fluconazole (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 3921.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

DISCLAIMER: MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.