



Suggested Formula	Hydrocortisone 2%, Hydroquinone 6%, Kojic Acid 4%, Salicylic Acid 4%, Tretinoin 0.01% Topical Gel (Suspension, 20 g)	FIN	F 006 615
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Tretinoin 2% Stock Solution †	0.10	mL				
Hydrocortisone (Micronized), USP	0.400	g				
Hydroquinone, USP	1.200	g				
Kojic Acid	0.800	g				
Salicylic Acid, USP	0.800	g				
Ethoxy Diglycol	1.0	mL				
Medisca CopaSil™	15.71	g				
† Tretinoin 2% Stock Solution						
Tretinoin (Retinoic Acid), USP	0.100	g				
Ethoxy Diglycol	4.0	mL				
Ethoxy Diglycol	q.s. to 5.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
Light Sensitive (protect from light whenever possible):	Hydrocortisone, Hydroquinone, Salicylic Acid Tretinoin, CopaSil™
Hygroscopic (protect from moisture whenever possible):	Ethoxy Diglycol
Oxygen sensitive (protect from air whenever possible):	Hydroquinone, Tretinoin
Heat Sensitive (protect from heat whenever possible):	Tretinoin
<u>Suggested Preparatory Guidelines</u>	
<input checked="" type="checkbox"/> Non-Sterile Preparation	<input type="checkbox"/> Sterile Preparation
<u>Processing Error / Testing Considerations:</u>	To account for processing error considerations during preparation, it is suggested to measure an additional 15 to 20% of the required quantities of ingredients.
<u>Special Instruction:</u>	Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn. All work must be carried out inside an appropriate fumehood. 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 20 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Tretinoin 2% Stock Solution † §	0.10	mL			
Hydrocortisone (Micronized), USP §	0.400	g			
Hydroquinone, USP §	1.200	g			
Kojic Acid	0.800	g			
Salicylic Acid, USP §	0.800	g			
Ethoxy Diglycol §	1.0	mL			
Medisca CopaSil™ §	15.71	g			
† Tretinoin 2% Stock Solution					
Tretinoin (Retinoic Acid), USP §	0.100	g			
Ethoxy Diglycol §	4.0	mL			
Ethoxy Diglycol §	q.s. to 5.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1. † **Tretinoin 2% 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 (4.0 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 (5.0 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.



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2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">-Hydrocortisone (Micronized)-Hydroquinone-Kojic Acid-Salicylic Acid <p>B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:</p> <ul style="list-style-type: none">-Tretinoin 2% Stock Solution (0.10 mL <i>plus</i> processing error adjustments)-Ethoxy Diglycol <p>C. Levigate the fine, homogeneous powder blend (Step 2A) with the homogeneous liquid-like solution (Step 2B).</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
3.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 2C) to the CopaSil™:</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p> <p>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.</p>
4.	<p><u>Product transfer:</u></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	6 months, as per USP*.	Packaging Requirements	Tightly closed, light-resistant container with topical applicator.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	8	Cap tightly after use.
	2	Keep out of reach of children.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	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.	10	Keep in a dry place.
	4	Keep at room temperature (20°C – 23°C).	11	Protect from light.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	12	For external use only.
	6	Do not allow to come into contact with eyes/ears/nose/mouth.	13	Do not touch the medication with your hands.
	7	Do not allow applicator tip to come into contact with surrounding tissue.		
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.			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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