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Suggested Formula	Benzocaine 20%, Lidocaine 6%, Tetracaine 4% Topical Cream (Emulsion,100 g)	FIN	F 009 529
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Benzocaine, USP	20.000	g				
Lidocaine, USP	6.000	g				
Tetracaine, USP	4.000	g				
Medisca VersaPro™ Cream Base	35.00	g				
Medisca VersaPro™ Cream Base	35.00	g				





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Narrow Therapeutic Index:	<i>Lidocaine</i>
Light Sensitive (protect from light whenever possible):	<i>Benzocaine, Tetracaine,</i>
Eutectic Mixture when combined:	<i>Lidocaine, Tetracaine</i>

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. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

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 (GFI) and Compliance Policy Guides (CPGs).

Lidocaine 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 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Benzocaine, USP §	20.000	g			
Lidocaine, USP	6.000	g			
Tetracaine, USP §	4.000	g			
Medisca VersaPro™ Cream Base	35.00	g			
Medisca VersaPro™ Cream Base	35.00	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Powder-liquid preparation:</u></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"> -Benzocaine -Lidocaine -Tetracaine <p>B. Levigate the fine, homogeneous powder blend (Step 1A) with the VersaPro™ Cream Base (35.00 <i>plus</i> processing error adjustments)</p> <p><u>End result:</u> Homogeneous cream-like dispersion.</p>
2.	<p><u>Medium Integration:</u></p> <p>A. Add additional VersaPro™ Cream Base (35.00 <i>plus</i> processing error adjustments) to the homogeneous cream-like dispersion (Step 1B).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous cream-like dispersion.</p> <p>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.</p>
3.	<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	150 days ongoing at 25°C ± 2°C, based on available stability studies through Medisca*	Packaging Requirements	Tightly closed, light-resistant ointment tube or wide-mouth container with metered topical applicator.	
	<p>The current BUD associated with this formula was updated as study results were received. Suggested BUD is based on the exact execution of the indicated ingredient list, quantities and procedures listed within this formulation.</p> <p>Note: <i>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.</i></p>			
Auxiliary Labels	1	Keep out of reach of children.	6	Use as directed. Do not exceed prescribed dose.
	2	Protect from light.	7	Keep in a dry place.
	3	For external use only.	8	Cap tightly after use.
	4	Keep at controlled room temperature (20°C – 25°C).	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	10	May impair mental and/or physical ability. Use care when operating a car or machinery.
Pharmacist Instructions	<p>Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.</p> <p>IMPORTANT: - Small batch is prepared due to inherent potential of systemic toxicity.</p> <ul style="list-style-type: none"> - Limits as to the total amount of product used should be established by a physician. - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas. - Continued application of this product might produce systemic side effects. Advise patient accordingly. <p>IMPORTANT: DRUG-DRUG INTERACTIONS EXIST BETWEEN DIFFERENT DRUG COMBINATIONS WITHIN THIS FORMULATION. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.</p>			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p>IMPORTANT: - Do not cover the site of application.</p> <ul style="list-style-type: none"> - The quantity of API administered is directly dependent on the quantity of product applied. 			



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