



Suggested Formula	Mupirocin 1% Nasal Mucoadhesive Liquid (Suspension, 50 mL)	FIN	F 008 266
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot No.	Expiry Date
Mupirocin, USP	TBD					
NovaFilm™	15.0	mL				
Benzalkonium Chloride Solution (50%), NF	0.04	mL				
Sterile Water for Injection, USP	30.0	mL				
Sterile Water for Injection, USP	q.s. to 50.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

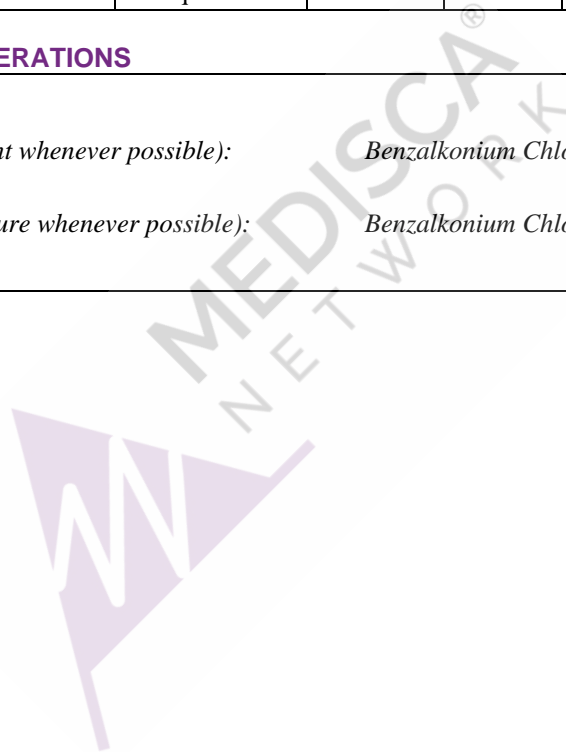
Ingredient-Specific Information

Light Sensitive (protect from light whenever possible):

Benzalkonium Chloride Solution

Hygroscopic (protect from moisture whenever possible):

Benzalkonium Chloride Solution





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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and sterility testing 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 797* and *USP 800* when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

All required personal protective equipment (sterile and hazardous if applicable), such as but not limited to, gowns, aprons, sleeves, gloves both inner and outer if applicable, shoe covers, hairnet, head cap, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

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.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

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).

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
Mupirocin, USP §	TBD				
NovaFilm™ §	15.0	mL			
Benzalkonium Chloride Solution (50%), NF §	0.04	mL			
Sterile Water for Injection, USP §	30.0	mL			
Sterile Water for Injection, USP §	q.s. to 50.0	mL			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique

1. Equipment sterilization:

Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.

2. Ingredient quantification:

A. Determine the quantity (in g) of Mupirocin required to make a Mupirocin 1% Nasal Liquid, batch size (50 mL):

Quantity of Mupirocin required for 50 mL	500 mg
DIVIDED BY	
Assay on anhydrous basis result (from certificate of analysis: $\mu\text{g}/\text{mg} = \text{mg}/\text{g}$)	_____ $\mu\text{g}/\text{mg}$
EQUALS	
i. Quantity of Mupirocin needed for 50 mL	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Mupirocin needed <i>plus</i> processing error adjustments	_____ g



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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Triturate the Mupirocin (amount determined in Step 2Aii) to form a fine, homogeneous powder.</p>		
4.	<p><u>Powder-liquid to Medium integration:</u></p> <p>A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (30.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none">-NovaFilm™-Fine, homogeneous powder (Step 3A)-Benzalkonium Chloride Solution (50%) <p><u>Specifications:</u> Continuously mix until all solid particles have completely dispersed.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>		
5.	<p><u>Filling to volume:</u></p> <p>A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>		
6.	<p><u>Product transferring:</u></p> <p>Aseptically transfer the finished product into the recommended dispensing container (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility testing.</p>		
7.	<p><u>Filter integrity test:</u></p> <p>Validate filter integrity by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.</p>		
8.	<p><u>Sterility testing:</u></p> <p>Validate the Test sample for sterility, in accordance to current USP 797 regulatory guidelines.</p>		



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP 797. BUD based on successful sterility test result.	Packaging Requirements	Sterile, tightly closed, light-resistant nasal spray bottle.
Auxiliary Labels	1 Use as directed. Do not exceed prescribed dose.	6	Shake well before use.
	2 Keep out of reach of children.	7	Do not use if product changes color.
	3 Equilibrate to room temperature before use.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4 Protect from light.	9	For nasal use only.
	5 Keep refrigerated (2°C – 8°C). Do not freeze.	10	
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.		



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REFERENCES

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