



Suggested Formula	Urea 10% Topical Ointment (Suspension, 15 g)	FIN	F 006 654
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Urea, USP	1.500	g				
Glycerin, USP	1.5	mL				
Medisca AlphaWash™	11.61	g				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible): Urea, Glycerin

**Heat Sensitive** (protect from heat whenever possible): Urea

#### 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 **15 to 20%** 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.



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**SUGGESTED PREPARATION (for 15 g)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Urea, USP §	1.500	g			
Glycerin, USP §	1.5	mL			
Medisca AlpaWash™	11.61	g			

§ Weigh / measure just prior to use.

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

Preparatory Instruction	
1.	<b><u>Powder-liquid preparation:</u></b>  A. Triturate the Urea to form a fine, homogeneous powder.  B. Levigate the fine homogeneous powder (Step 1A) with the Glycerin.  <u>End result:</u> Homogeneous paste-like dispersion.
2.	<b><u>Powder-liquid to medium integration:</u></b>  A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the AlpaWash™.  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous ointment-like dispersion.  B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
3.	<b><u>Product transfer:</u></b>  Transfer the final product into the specified dispensing container (see “Packaging Requirements”).



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	- Tightly closed container. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Cap tightly after use.
	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.	7	Keep at room temperature (20°C – 23°C).
	4	For external use only.		
Pharmacist Instructions	<p><b>Note: This non-sterile formulation, as per USP &lt;3&gt;, should not be applied to an open wound or burned area. If this formulation will be applied to an open wound or burned area, it must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP &lt;797&gt;. Also, in consideration of the overall formulation make-up and following the manufacturer's specifications, the suggested method of end-stage sterilization is gamma irradiation. The resulting BUD will be 30 days, as per USP &lt;797&gt;, based on a successful sterility test result.</b></p> <p>Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.</p>			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p><b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.</p>			

\* 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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## REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 265.
2.	Urisc 40. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 3156.
3.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 324.
4.	Urea. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1620.
5.	Urea (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #10 052.
6.	Urea. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 493.
7.	Urea (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 5720.
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