MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net



| Suggested Formula | Diclofenac Sodium 10% Topical Gel (Suspension, 30 g) | FIN | F 008 972 |
|---|---|---|---|

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Diclofenac Sodium, USP | 3.000 | g | | | | |
| Propylene Glycol, USP | 1.500 | g | | | | |
| Medisca VersaPro™ Anhydrous Base | 25.50 | g | | | | |

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## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

***Hygroscopic*** *(protect from moisture whenever possible):* *Diclofenac Sodium, Propylene Glycol*

***Light Sensitive*** *(protect from light whenever possible):* *Diclofenac Sodium, Propylene Glycol*

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 **12 to 15%** 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 (GFIs) 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 30 g)

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing | Qty. | Unit | Multiplication factor (*): ____ | Processing Error | Qty. to measure |
|---|---|---|---|---|---|
| Diclofenac Sodium, USP § | 3.000 | g | | | |
| Propylene Glycol, USP § | 1.500 | g | | | |
| Medisca VersaPro™ Anhydrous Base | 25.50 | g | | | |

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

| Preparatory Instruction | |
|---|---|
| 1. | **Powder-liquid preparation:**<br>A. Triturate the Diclofenac Sodium to form a fine, homogeneous powder.<br>B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol.<br>End result: Homogeneous paste-like dispersion. |
| 2. | **Medium incorporation:**<br>A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the VersaPro™ Anhydrous Base.<br>Specifications: Continuously mix, using high-shear mixing techniques.<br>End result: Homogeneous gel-like dispersion.<br>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform. |
| 3. | **Product transfer:**<br>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 795*. | Packaging Requirements | | - Tightly closed, light-resistant ointment tube/jar.<br>- To be administered with a metered-dose measuring device. |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | | 6 | Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants. |
| | 2 | Keep out of reach of children. | | 7 | Keep at controlled room temperature (20°C – 25°C). |
| | 3 | For external use only. | | 8 | Protect from light. |
| | 4 | May impair mental and/or physical ability. Use care when operating a car or machinery. | | 9 | Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use. |
| | 5 | Cap tightly after use. | | 10 | Keep in a dry place. |
| 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.<br>**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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## REFERENCES


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