MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net



| Suggested Formula | Fluticasone Propionate 1%, Pentoxifylline 5%, Tranilast 1% Topical Gel (Suspension, 15 g) | FIN | F 006 470 |
|---|---|---|---|

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Fluticasone Propionate, USP | 0.150 | g | | | | |
| Pentoxifylline, USP | 0.750 | g | | | | |
| Tranilast | 0.150 | g | | | | |
| Ethoxy Diglycol | 0.7 | mL | | | | |
| Medisca CopaSil™ | 13.23 | g | | | | |

## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

***Light Sensitive*** *(protect from light whenever possible):* *Fluticasone Propionate, Pentoxifylline, Tranilast, CopaSil™*

***Hygroscopic*** *(protect from moisture whenever possible):* *Ethoxy Diglycol*

Heat 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net



| Suggested Formula | Fluticasone Propionate 1%, Pentoxifylline 5%, Tranilast 1% Topical Gel (Suspension, 15 g) | FIN | F 006 470 |
|---|---|---|---|

## 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 |
|---|---|---|---|---|---|
| Fluticasone Propionate, USP § | 0.150 | g | | | |
| Pentoxifylline, USP § | 0.750 | g | | | |
| Tranilast § | 0.150 | g | | | |
| Ethoxy Diglycol § | 0.7 | mL | | | |
| Medisca CopaSil™ | 13.23 | 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><br>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:<br><br>-Fluticasone Propionate<br>-Pentoxifylline<br>-Tranilast<br><br>B. Levigate the fine homogeneous powder blend (Step 1A) with the Ethoxy Diglycol.<br><br>End result: Homogeneous paste-like dispersion. |
| 2. | **Powder-liquid to medium integration:**<br><br>A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the CopaSil™.<br><br>Specifications: Continuously mix, using high-shear mixing techniques.<br><br>End result: Homogeneous gel-like dispersion.<br><br>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform. |
| 3. | **Product transfer:**<br><br>Transfer the final product into the specified dispensing container (see “Packaging Requirements”). |

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net



| Suggested Formula | Fluticasone Propionate 1%, Pentoxifylline 5%, Tranilast 1% Topical Gel (Suspension, 15 g) | FIN | F 006 470 |
|---|---|---|---|

## SUGGESTED PRESENTATION

| | | | | | |
|---|---|---|---|---|---|
| Estimated Beyond-Use Date | 6 months, as per USP*. | | Packaging Requirements | - Tightly closed, light-resistant container.<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 | 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. | 8 | May impair mental and/or physical ability. Use care when operating a car or machinery. | |
| | 4 | Keep at room temperature (20°C – 23°C). | 9 | Keep in a dry place. | |
| | 5 | For external use only. | 10 | Protect from light. | |
| 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><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.**

## REFERENCES


1. Gels. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 285.
2. Flovent HFA. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2015*: 1239.
3. Pentoxifylline. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2015*: 2251.
4. Diethylene Glycol Monoethyl Ether. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 7th Edition.* American Pharmaceutical Association; 2012: 256.
5. Fluticasone Propionate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1533.
6. Pentoxifylline. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1367.
7. Tranilast. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1149.

| | | | |
|---|---|---|---|
| Suggested Formula | Fluticasone Propionate 1%, Pentoxifylline 5%, Tranilast 1% Topical Gel (Suspension, 15 g) | FIN | F 006 470 |


| | |
|---|---|
| 8. | Fluticasone Propionate (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4240. |
| 9. | Pentoxifylline (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #7249. |
| 10. | Tranilast (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #9731. |
| 11. | Fluticasone Propionate. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 215. |
| 12. | Pentoxifylline. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 377. |
| 13. | Fluticasone Propionate (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 3578. |
| 14. | Pentoxifylline (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 4812. |
| 15. | Fluticasone. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 997. |
| 16. | Pentoxifylline Systemic. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2419. |
| 17. | USP <795>. *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559. |