**CRITIC AID CLEAR AF- miconazole nitrate ointment**
**Coloplast Manufacturing US, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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***Critic-Aid® Clear AF***
**Antifungal Ointment**
**Clear Moisture Barrier With Antifungal**

For Perineal
Skin Irritation Due To
Fungal Infection

- Adheres to denuded skin
- Easy to apply and remove
- Treats topical fungal infections

***Drug Facts***

***Active ingredient***

Miconazole nitrate, 2%

***Purpose***

Antifungal

***Uses*** For effective treatment of jock itch. Relieves itching, scaling, irritation, redness and discomfort.

***Warnings***

***When using this product***

- avoid contact with eyes
- do not use on children under 2 years of age unless directed by a doctor

**Stop using this product and ask a doctor** if irritation occurs or there is no improvement within 2 weeks.

**For external use only. Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- clean the affected area and dry thoroughly
- apply thin layer of product over affected area twice daily (morning and night), or as directed by a doctor
- supervise children in the use of this product.

Use daily for 2 weeks.

If condition persists, consult a doctor. This product is not effective on scalp or nails.

***Inactive ingredients***

cellulose gum, dimethicone, petrolatum, tocopheryl acetate

Patent Pending

See crimp for lot no. and expiration date

Manufactured by: Coloplast A/S DK-3050 Humlebaek, Denmark
Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A.

1-800-533-0464 www.us.coloplast.com **Product # 7572**


L7-1349

*PRINCIPAL DISPLAY PANEL - NET WT. 5 OZ. (142g)*

NDC 11701-067-14

*Critic-Aid® Clear AF*

Antifungal Ointment

Clear Moisture Barrier With Antifungal

For Perineal

Skin Irritation Due To

Fungal Infection

**Coloplast**

NET WT. 5 OZ. (142 g)

NDC 11701-067-23

Critic-Aid® Clear AF

Antifungal Ointment

# Clear Moisture Barrier with Antifungal

For Perineal Skin Irritation Due to Fungal Infection

AF

Coloplast

NET WT. 2 OZ. (57 g)

SCP SAMPLE

0 12345 67890 5

## Drug Facts

**Active ingredients** **Purpose**

Miconazole nitrate, 2% . . . . . .Antifungal

**Uses** For effective treatment of jock itch. Relieves itching, scaling, irritation, redness and discomfort.

**Warnings**

**When using this product:** avoid contact with eyes ■ do not use on children under 2 years of age unless directed by a doctor. **Stop using this product and ask a doctor** if irritation occurs or there is no improvement within 2 weeks.

**For external use only. Keep this and all drugs out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ■ clean the affected area and dry thoroughly ■ apply thin layer of product over affected area twice daily (morning and night), or as directed by a doctor ■ supervise children in the use of this product ■ use daily for 2 weeks ■ if condition persists, consult a doctor ■ this product is not effective on scalp or nails.

**Inactive ingredients** cellulose gum, dimethicone, petrolatum, tocopheryl acetate

Patent Pending

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1-800-533-0464 www.us.coloplast.com
**Product #7571** ©2007, Coloplast Corp.
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REUSE RECYCLE

G7-1348

3-11701-06723-1

# CRITIC AID CLEAR AF

miconazole nitrate ointment

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11701-067 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MICONAZOLE NITRATE** (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 20 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| Ingredient Name | Strength |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |
| **.ALPHA.-TOCOPHEROL ACETATE, D-** (UNII: A7E6112E4N) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| **1** | NDC:11701-067-22 | 4 g in 1 PACKET; Type 0: Not a Combination Product | 06/15/2009 | |
| **2** | NDC:11701-067-23 | 57 g in 1 TUBE; Type 0: Not a Combination Product | 06/15/2009 | |
| **3** | NDC:11701-067-14 | 142 g in 1 TUBE; Type 0: Not a Combination Product | 06/15/2009 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part333C | 06/15/2009 | |

## Labeler - Coloplast Manufacturing US, LLC (110326675)

## Registrant - Coloplast Corp (847436391)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Coloplast Manufacturing US, LLC | | 110326675 | MANUFACTURE(11701-067) |

Revised: 2/2018 Coloplast Manufacturing US, LLC