



**LABELLING STANDARD FOR MICONAZOLE, CLOTRIMAZOLE  
AND NAFTIFINE FOR TREATING FUNGAL SKIN INFECTIONS.**

**CATEGORY:** Naftifine and Imidazole antifungal agents

**APPLICATION:** Cream, gel and liquid forms of antifungal agents for the treatment of fungal infections of the skin.

**MEDICINAL INGREDIENTS  
and CONCENTRATIONS:**

The finished product and all ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this monograph consist of the following ingredients when used singly within the established limits given:

clotrimazole nitrate, 1%, cream\* and solution  
miconazole nitrate, 2%, cream\* and solution  
naftifine hydrochloride, 1%, cream or gel

**NOTE:** these ingredients are subject to the requirements of Division 8, Part C of the Regulations to the Food and Drugs Act. Established OTC antifungal ingredients are included in the Labelling Standard for Topical Antifungals

\* see also Labelling Standard for Intravaginal miconazole and clotrimazole

**ADEQUATE DIRECTIONS FOR USE:**

**Indications:**

For the treatment of athlete's foot (tinea pedis), jock-itch (tinea-cruris) or ringworm (tinea corporis).

**Other acceptable claims**

- . kills the fungus that causes athlete's foot/jock itch/ringworm
- . relieves itching, scaling, burning and soreness of athlete's foot
- . cures athlete's foot/jock itch/ringworm when used for the full treatment period (four weeks)



### **Claims not acceptable**

. kills athlete's foot fungus on contact

### **Dosage Directions:**

For the treatment of athlete's foot, jock itch or ringworm -

1. Cleanse skin with soap and water and dry thoroughly.
2. a) Rub in a thin layer\* on affected area twice daily for full treatment period - if there is no improvement within 2 weeks, consult a physician - otherwise, continue treatment for a week or two after symptoms have disappeared (up to a maximum of 4 weeks) - jock itch and ringworm usually require 2 weeks to resolve while athlete's foot may require 4 weeks.

\* Use "apply to affected area...." for solutions

For athlete's foot -

2. b) (in applying medication) Pay special attention to spaces between toes.
3. Wear well fitting, ventilated shoes and cotton socks.

### **Warnings:**

1. For external use only.
2. Do not use on children under 2 years of age.
3. Do not use for infections of the scalp or nails.
4. Avoid contact with eyes: if this happens, rinse thoroughly with water.
5. If new irritation occurs, consult a physician.
6. Do not use while pregnant or nursing except on the advice of a physician.

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**NOTE:** This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

**REFERENCES:**

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8. Gilman, A.G., Rall, T.W., Nies, A.S., Taylor, P. (Ed.) The Pharmacological Basis of Therapeutics, 8th Ed. Pergamon Press, pp. 1176-1177 and 1585, 1990.
9. Avery, G.S. (Ed.), Drug Treatment: Principles and Practice of Clinical Pharmacology and Therapeutics. Adis Press, pp. 1138,1236 1980.
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