



LABELLING STANDARD
ANTIFUNGALS (TOPICAL)

I) **Description:**

This labelling standard applies to products in cream, ointment, lotion, gel, powder, spray powder, aerosol liquid, solution, foam, or soap form intended to treat jock itch or ringworm. The medicinal ingredients and their concentrations in applicable products are restricted to those specified in this standard. The medicinal ingredients must be identified on product labelling by the names given in this standard.

Definitions

An antifungal agent is a drug which either kills or inhibits the growth and reproduction of fungal cells.

A dermatophyte is a fungus that invades and lives upon the skin or in the hair or nails.

Jock Itch is a chronic and recurrent dermatophyte infection which affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.

Ringworm is a skin infection caused by dermatophytic fungi.

Special Note:

In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

II) **Pharmaceutical Quality:**

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

i) Pharmacopoeial standards for formulated antifungal preparations that are contained in Schedule B publications are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.

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- ii) Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient(s) including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. It is recommended that antimicrobial preservative effectiveness be determined in order to establish that the product is capable of resisting microbial contamination.

III) **Ingredients:**

a) **Single Medicinal ingredients:**

i)	Chlorphenesin	0.5 - 1 %
ii)	Clioquinol (Iodochlorhydroxyquin)	3 %
iii)	Haloprogin	1 %
iv)	Povidone-Iodine	10 %
v)	Tolnaftate	1 %
vi)	Undecylenic acid	10 - 25 %
vii)	Calcium undecylenate	10 - 25 %
viii)	Copper undecylenate	10 - 25 %
ix)	Zinc undecylenate	10 - 25 %

b) **Combinations of Medicinal Ingredients:**

Two or more of the following may be combined provided that the combined ingredients provide a total undecylenate concentration of 10-25 %:

- i) undecylenic acid
- ii) calcium undecylenate
- iii) copper undecylenate
- iv) zinc undecylenate

IV) **Labelling:**

- a) 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* must also be met.

b) **Directions for Use:**

i) **Indications**

The primary indication shall be

For the treatment of jock itch (tinea cruris) or ringworm (tinea corporis)

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The following statements are also acceptable where appropriate:

- 1) kills jock itch or ringworm fungus;
- 2) cures jock itch/ringworm (acceptable provided a direction, "to use daily for the full treatment period" is specified);
- 3) relieves (itching, scaling, burning, cracking, redness, soreness, irritation) of jock itch or ringworm.

ii) **Unacceptable Claims:**

kills fungus on contact

iii) **Dosage Directions:**

For the treatment of jock itch or ringworm

- 1) cleanse skin with soap and water and dry thoroughly;
- 2) apply (spray) a thin layer over affected area morning and night for full treatment period (See **Warnings**)

iv) **Warnings:**

- 1) for external use only;
- 2) do not use in children under 2 years of age, except under advice of a doctor (or a direction that the product should be used by adults and children **over 2 years**);
- 3) avoid contact with eyes; if this happens, rinse thoroughly with water;
- 4) if irritation occurs or if there is no improvement following the full treatment period of 2 weeks (for jock itch) or 4 weeks (for ringworm), discontinue use and consult a doctor;
- 5) do not use for infections of the scalp.

V) **REFERENCES:**

- 1) **United States Federal Register** Vol. 47, No. 56 March, 1982 pp 12480-12566. Topical Antifungal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph.
- 2) **United States Federal Register** Vol. 54, No. 237 December, 1989 pp 51136-51160. Topical Antifungal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph.
- 3) **Self-Medication. A Reference for Health Professionals**, 3rd

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- Edition, 1988, Canadian Pharmaceutical Association.
- 4) **American Handbook of Nonprescription Drugs**, 9th Edition, 1990, American Pharmaceutical Association.
 - 5) **Canadian Drug Identification Code Book**, 18th Edition, 1992, Health and Welfare Canada.
 - 6) **Compendium of Pharmaceuticals and Specialties**, 27th Edition, 1992, Canadian Pharmaceutical Association.
 - 7) **Drugdex**, Vol. 73, 1974-1992, Micromedex Inc.
 - 8) **Remington's Pharmaceutical Science**, 18th Edition, 1990, Philadelphia College of Pharmaceutical Sciences.
 - 9) **Martindale, The Extra Pharmacopoeia**, 29th Edition, 1989, The Pharmaceutical Press, London.
 - 10) **Goodman and Gilman's The Pharmacological Basis of Therapeutics**, 8th Edition, 1990. Gilman, A.G., Rall, T.W., Nies, A.S. and Taylor, P. (Eds), Pergamon Press, Inc., NY.
 - 11) **Drug Facts and Comparisons**, 1989. J.B. Lippincott Company, Facts and Comparisons Division, St. Louis, Missouri.
 - 12) **Drug Information for the Health Care Professional**, 12th Edition, 1992, The United States Pharmacopoeial Convention, Inc., Rockville, MD.
 - 13) Wong, E. and Grant, D. 1984 Antifungal agents - use in athlete's foot. **On Continuing Practice** 11:2-6.
 - 14) **AMA Drug Evaluations Annual**, 1992, American Medical Association.
 - 15) **F. D. C. Reports**, December 18, 1989. pp. 17-18.

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Appendix I
Formulated Preparations

Proper Name	USP 1995	BP 1993	BPC 1976
chlorphenesin			X
clioquinol	X		X
clioquinol cream	X	X	
clioquinol ointment	X		
compound clioquinol topical powder	X		
haloprogin	X		
haloprogin cream	X		
haloprogin topical solution	X		
povidone-iodine	X		
povidone-iodine ointment	X		
povidone-iodine solution		X	
povidine-Iodine Cleansing Solution	X		
povidone-iodine topical solution	X		
tolnaftate	X		X
tolnaftate topical aerosol powder	X		
tolnaftate cream	X		
tolnaftate gel	X		
tolnaftate topical powder	X		
tolnaftate topical solution	X		
undecylenic acid	X		X
compound undecylenic acid ointment	X		
calcium undecylenate	X		
zinc undecylenate	X		X

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