U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M005: Topical Antifungal Drug Products for Over-the-Counter Human Use (Posted December 16, 2021)[1]

Part A—General Provisions

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SOURCE: 58 FR 49898, Sept. 23, 1993, unless otherwise noted.

Part A—General Provisions

§ M005.1 Scope

An over-the-counter antifungal drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this OTC monograph and each general condition established in 21 CFR 330.1.

§ M005.3 Definitions

As used in this OTC monograph:

(a) Antifungal. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.

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[1] Final Administrative Order (OTC000017), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(b) Athlete's foot. An infection of the feet caused by certain dermatophytic fungi.

(c) Dermatophyte. A fungus that invades and lives upon the skin or in the hair or nails.

(d) Fungus. Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.

(e) Jock itch. A chronic and recurrent infection caused by certain dermatophytic fungi; 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.

(f) Ringworm. A skin infection caused by certain dermatophytic fungi.

Part B—Active Ingredients

§ M005.10 Antifungal active ingredients

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Clioquinol 3 percent.

(b) Haloprogin 1 percent.

(c) Miconazole nitrate 2 percent.

(d) Povidone-iodine 10 percent.

(e) Tolnaftate 1 percent.

(f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio that provides a total undecylenate concentration of 10 to 25 percent.

(g) Clotrimazole 1 percent.

[58 FR 49898, Sept. 23, 1993, as amended at 67 FR 5943, Feb. 8, 2002]

Part C—Labeling

§ M005.50 Labeling of antifungal drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antifungal.”

(b) Indications. The labeling of the product states, under the heading “Uses,” the phrase listed in § M005.50(b)(1)(i) and may contain the additional phrase listed in § M005.50(b)(1)(ii). Other truthful and nonmisleading statements, describing only the indications for use that have been established in § M005.50(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(1) For products containing any ingredient identified in § M005.10 labeled for the treatment of athlete's foot, jock itch, and ringworm.

(i) (Select one of the following: “Treats,” “For the treatment of,” “For effective treatment of,” “Cures,” “For the cure of,” “Clears up,” or “Proven clinically effective in the treatment of”) “most” (select one condition from any one or more of the following groups of conditions:

(A) “Athlete's foot,” “athlete's foot (dermatophytosis),” “athlete's foot (tinea pedis),” or “tinea pedis (athlete's foot)”;

(B) “Jock itch,” “jock itch (tinea cruris),” or “tinea cruris (jock itch)”; or

(C) “Ringworm,” “ringworm (tinea corporis),” or “tinea corporis (ringworm).”)

(ii) In addition to the information identified in § M005.50(b)(1)(i), the labeling of the product may contain the following statement: (Select one of the following: “Relieves,” “For relief of,” “For effective relief of,” or “Soothes,”) (select one or more of the following: “Itching,” “scaling,” “cracking,” “burning,” “redness,” “soreness,” “irritation,” “discomfort,” “chafing associated with jock itch,” “itchy, scaly skin between the toes,” or “itching, burning feet”).

(2) For products containing the ingredient identified in § M005.10(e) labeled for the prevention of athlete's foot.

(i) (Select one of the following: “Clinically proven to prevent,” “Prevents,” “Proven effective in the prevention of,” “Helps prevent,” “For the prevention of,” “For the prophylaxis (prevention) of,” “Guards against,” or “Prevents the recurrence of”) “most” (select one of the following: “Athlete's foot,” “athlete's foot (dermatophytosis),” “athlete's foot (tinea pedis),” or “tinea pedis (athlete's foot)”) “with daily use.”

(ii) In addition to the information identified in § M005.50(b)(2)(i), the labeling of the product may contain the following statement: “Clears up most athlete's foot infection and with daily use helps keep it from coming back.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) For products containing any ingredient identified in § M005.10.

(i) “Do not use on children under 2 years of age unless directed by a doctor.”

(ii) “For external use only.”

(iii) “Avoid contact with the eyes.”

(2) For products labeled according to § M005.50(b)(1) for the treatment of athlete's foot and ringworm. “If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.”

(3) For products labeled according to § M005.50(b)(1) for the treatment of jock itch. “If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.”

(4) For products labeled according to § M005.50(b)(2) for the prevention of athlete's foot. “If irritation occurs, discontinue use and consult a doctor.”

(5) For products containing the ingredient identified in § M005.10(a) labeled according to § M005.50(b)(1). The following statements must appear in boldface type as the first warnings under the “Warnings” heading.

(i) “Do not use on children under 2 years of age.” (This warning is to be used in place of the warning in § M005.50(c)(1)(i)).

(ii) “Do not use for diaper rash.”

(d) Directions. The labeling of the product contains the following statements under the heading "Directions":

(1) For products labeled according to § M005.50(b)(1) for the treatment of athlete's foot, jock itch, and ringworm. [Select one of the following: "Clean" or "Wash"] "the affected area and dry thoroughly. Apply" (the word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails."

(2) For products labeled according to § M005.50(b)(2) for the prevention of athlete's foot. "To prevent athlete's foot," (select one of the following: "clean" or "wash") "the feet and dry thoroughly. Apply" (the word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in § M005.50.

[58 FR 49898, Sept. 23, 1993, as amended at 65 FR 52305, Aug. 29, 2000]

Part D—Professional Use

§ M005.80 Professional labeling

The labeling provided to health professionals (but not to the general public) may contain the following additional indication:

For products containing haloprogin or miconazole nitrate identified in §§ M005.10(b) and (c). "For the treatment of superficial skin infections caused by yeast (*Candida albicans*)."