U.S. Food and Drug Administration

Over-the-Counter Monograph M030: Corn and Callus Remover Drug Products for Over-the-Counter Human Use (Posted September 20, 2021)[1]

Part A—General Provisions

Part B—Active Ingredients

Part C—Labeling

SOURCE: 55 FR 33261, Aug. 14, 1990, unless otherwise noted.

Part A—General Provisions

§ M030.1 Scope

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

§ M030.3 Definitions

As used in this OTC monograph:

(a) Corn and callus remover drug product. A topical agent used for the removal of corns and calluses.

[1] Final Administrative Order OTC000004, effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(b) Collodion-like vehicle. A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) Plaster vehicle. A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

Part B—Active Ingredients

§ M030.10 Corn and callus remover active ingredients

The product consists of any of the following active ingredients within the specified concentrations and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

Part C—Labeling

§ M030.50 Labeling of corn and callus remover 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 a "corn and callus remover."

(b) Indications. The labeling of the product states, under the heading "Uses," the phrase listed in § M030.50(b)(1) and may contain the additional phrase listed in § M030.50(b)(2). Other truthful and nonmisleading statements, describing only the indications for use that have been established in § M030.50(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 the removal of corns and calluses."

(2) In addition to the information identified in § M030.50(b)(1), the labeling of the product may contain the following statement: "Relieves pain by removing corns and calluses."

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

(1) For products containing any ingredient identified in § M030.10.

(i) "For external use only."

(ii) “Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.”

(iii) “If discomfort persists, see your doctor or podiatrist.”

(2) For any product formulated in a flammable vehicle.

(i) The labeling should contain an appropriate flammability signal word, e.g., “extremely flammable,” “flammable,” “combustible,” consistent with 16 CFR 1500.3(b)(10).

(ii) “Keep away from fire or flame.”

(3) For any product formulated in a volatile vehicle. “Cap bottle tightly and store at room temperature away from heat.”

(4) For any product formulated in a collodion-like vehicle.

(i) “If product gets into the eye, flush with water for 15 minutes.”

(ii) “Avoid inhaling vapors.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) For products containing salicylic acid identified in § M030.10(a). “Wash affected area and dry thoroughly.” (If appropriate: “Cut plaster to fit corn/callus.”) “Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed).” (Optional: “May soak corn/callus in warm water for 5 minutes to assist in removal.”)

(2) For products containing salicylic acid identified in § M030.10(b). “Wash affected area and dry thoroughly. Apply” (select one of the following, as appropriate: “one drop” or “small amount”) “at a time with” (select one of the following, as appropriate: “applicator” or “brush”) “to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed).” (Optional: “May soak corn/callus in warm water for 5 minutes to assist in removal.”)

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in § M030.50.

[55 FR 33261, Aug. 14, 1990, as amended at 57 FR 44494, Sept. 28, 1992]