

U.S. Food and Drug Administration

**Over-the-Counter (OTC) Monograph M029:
Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use
(Posted October 1, 2021)¹**

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SOURCE: 68 FR 24348, May 7, 2003, unless otherwise noted.

Part A—General Provisions

§ M029.1 Scope

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

§ M029.3 Definitions

As used in this OTC monograph:

(a) Ingrown toenail relief drug product. A drug product applied to an ingrown toenail that relieves pain or discomfort either by softening the nail or by hardening the nail bed.

¹ Final Administrative Order (OTC000011), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(b) Retainer ring. A die cut polyethylene foam pad coated on one side with medical grade acrylic pressure-sensitive adhesive. The retainer ring has slots, center-cut completely through the foam with the cut of sufficient size to allow for localization of an active ingredient in a gel vehicle to a specific target area. The retainer ring is used with adhesive bandage strips to place over the retainer ring to hold it in place.

Part B—Active Ingredient

§ M029.10 Ingrown toenail relieve active ingredient

The active ingredient of the product is sodium sulfide 1 percent in a gel vehicle. The gel vehicle is an aqueous, semisolid system with large organic molecules interpenetrated with a liquid.

Part C—Labeling

§ M029.50 Labeling of ingrown toenail relief drug products

(a) Statement of identity. The labeling of the product contains the established name of the product, if any, and identifies the product as an “ingrown toenail relief product” or as an “ingrown toenail discomfort reliever.”

(b) Indications. The labeling of the product states, under the heading “Use,” the following: “for temporary relief of” [select one or both of the following: ‘pain’ or ‘discomfort’] “from ingrown toenails”. Other truthful and nonmisleading statements, describing only the use that has been established and listed in § M029.50(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)).

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

- (1) “For external use only” in accord with 21 CFR 201.66(c)(5)(i).
- (2) “Do not use [bullet]² on open sores”.
- (3) “Ask a doctor before use if you have [bullet] diabetes [bullet] poor circulation [bullet] gout”.
- (4) “When using this product [bullet] use with a retainer ring”.

² See 21 CFR 201.66(b)(4) for definition of bullet.

(5) “Stop use and ask a doctor if [bullet] redness or swelling of your toe increases [bullet] discharge is present around the nail [bullet] symptoms last more than 7 days or clear up and occur again within a few days”.

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

(1) “[Bullet] adults and children 12 years and over:”

(i) “[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the area where the ingrown nail and the skin meet. Smooth ring down firmly. [bullet] apply enough gel product to fill the slot in the ring [bullet] place round center section of bandage strip directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toes.”

(ii) “[Bullet] repeat twice daily (morning and night) for up to 7 days until discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed”.

(2) “[Bullet] children under 12 years: ask a doctor”.