

**U.S. Food and Drug Administration**

**Over-the-Counter (OTC) Monograph M026:  
Deodorant Drug Products for Internal Use for Over-the-Counter Human Use  
(Posted November 23, 2021)<sup>1</sup>**

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SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

**Part A—General Provisions**

**§ M026.1 Scope**

An over-the-counter (OTC) deodorant drug product for internal use in a form suitable for oral 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.

**§ M026.3 Definitions**

As used in this OTC monograph:

- (a) Colostomy. An external operative opening of the colon.
- (b) Deodorant for internal use. An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

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<sup>1</sup> Final Administrative Order (OTC000016), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(c) Ileostomy. An external operative opening from the ileum.

(d) Incontinence. An inability to retain urine or feces.

## **Part B—Active Ingredients**

### **§ M026.10 Active ingredients for deodorant drug products for internal use**

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § M026.50(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

## **Part C—Labeling**

### **§ M026.50 Labeling of deodorant drug products for internal use**

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “deodorant for internal use” or as a “colostomy or ileostomy deodorant.”

(b) Indications. The labeling of the product states, under the heading “Uses,” any of the phrases listed in § M026.50(b) as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M026.50(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 bismuth subgallate identified in § M026.10(a). “An aid to reduce odor from a colostomy or ileostomy.”

(2) For products containing chlorophyllin copper complex identified in § M026.10(b).

(i) “An aid to reduce odor from a colostomy or ileostomy.”

(ii) “An aid to reduce fecal odor due to incontinence.”

(c) Warnings. For products containing chlorophyllin copper complex identified in § M026.10(b), the labeling of the product contains the following warnings under the heading “Warnings”:

(1) “If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor.”

(2) The warning required by 21 CFR 330.1(g) concerning overdose is not required on products containing chlorophyllin copper complex identified in § M026.10(b).

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

(1) For products containing bismuth subgallate identified in § M026.10(a). Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) For products containing chlorophyllin copper complex identified in § M026.10(b). Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.