

§ 357.152

Weight	Dosage (taken as a single dose) ¹
163 to 187 pounds	875 milligrams.
188 pounds and over	1,000 milligrams.

¹Depending on the product, the label should state the quantity of drug as a liquid measurement (e.g., teaspoonful) or as the number of dosage units (e.g., tablets) to be taken for the varying body weights. (If appropriate, it is recommended that a measuring cup graduated by body weight and/or liquid measurement be provided with the product.) Manufacturers should present this information as appropriate for their product and may vary the format of this chart as necessary.

(2) “Read package insert carefully before taking this medication. Take only according to directions and do not exceed the recommended dosage unless directed by a doctor. Medication should only be taken on time as a single dose; do not repeat treatment unless directed by a doctor. When one individual in a household has pinworms, the entire household should be treated unless otherwise advised. See Warnings. If any worms other than pinworms are present before or after treatment, consult a doctor. If any symptoms or pinworms are still present after treatment, consult a doctor.

(3) “This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice. Use of a laxative is not necessary prior to, during, or after medication.”

(e) *Optional wording.* The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

[51 FR 27759, Aug. 1, 1986; 52 FR 7831, Mar. 13, 1987, as amended at 53 FR 35810, Sept. 15, 1988]

§ 357.152 Package inserts for anthelmintic drug products.

The labeling of the product contains a consumer package insert which includes the following information:

(a) A discussion of the symptoms suggestive of pinworm infestation, including a statement that pinworms must be visually identified before taking this medication.

(b) A detailed description of how to find and identify the pinworm.

(c) A commentary on the life cycle of the pinworm.

(d) A commentary on the ways in which pinworms may be spread from

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person to person and hygienic procedures to follow to avoid such spreading.

(e) The appropriate labeling information contained in § 357.150

(Collection of information requirement approved by the Office of Management and Budget under control number 0910–0232)

[51 FR 27759, Aug. 1, 1986, as amended at 52 FR 2515, Jan 23, 1987]

§ 357.180 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain an additional indication: “For the treatment of common roundworm infestation.”

Subpart C—Cholecystokinetic Drug Products

§ 357.201 Scope.

(a) An over-the-counter cholecystokinetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart in addition to each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[48 FR 27005, June 10, 1983]

§ 357.203 Definition.

As used in this subpart:

Cholecystokinetic drug product. A drug product that causes contraction of the gallbladder and is used during the course of diagnostic gallbladder studies (cholecystography).

[48 FR 27005, June 10, 1983]

§ 357.210 Cholecystokinetic active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

(a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrogenated with a melting

point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	0.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	0.1
Arachidic acid	0.5
Behenic acid	0.2

[54 FR 8321, Feb. 28, 1989]

§ 357.250 Labeling of cholecystokinetic 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 “gallbladder diagnostic agent.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following: “For the contraction of the gallbladder during diagnostic gallbladder studies.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* [Reserved]

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

(1) “Take only when instructed by a doctor.”

(2) *For products containing 50-percent aqueous emulsion of corn oil.*

(i) “Shake well before using.”

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) *For products containing hydrogenated soybean oil.* Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes be-

fore diagnostic gallbladder x-ray or as directed by a doctor.

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

[48 FR 27005, June 10, 1983, as amended at 51 FR 16267, May 1, 1986; 52 FR 7830, Mar. 13, 1987; 54 FR 8321, Feb. 28, 1989]

§ 357.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in §357.210: *Indication.* “For visualization of biliary ducts during cholecystography.”

[54 FR 8321, Feb. 28, 1989]

Subparts D–H [Reserved]

Subpart I—Deodorant Drug Products for Internal Use

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

§ 357.801 Scope.

(a) An over-the-counter 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 subpart and each general condition established in §330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 357.803 Definitions.

As used in this subpart:

(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.

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

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