U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M024: Anthelmintic Drug Products for Over-the-Counter Human Use (Posted December 16, 2021)[1]

Part A—General Provisions

Part B—Active Ingredients

Part C—Labeling

Part D—Professional Use

SOURCE: 51 FR 27759, Aug. 1, 1986, unless otherwise noted.

Part A—General Provisions

§ M024.1 Scope

An over-the-counter (OTC) anthelmintic drug product 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.

§ M024.3 Definition

As used in this OTC monograph:

Anthelmintic. An agent that is destructive to worms.

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[1] Final Administrative Order (OTC000018), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

Part B—Active Ingredients

§ M024.10 Anthelmintic active ingredient

The active ingredient of the product is pyrantel pamoate when used within the dosage limits established in § M024.50(d)(1).

Part C—Labeling

§ M024.50 Labeling of anthelmintic 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 "pinworm treatment."

(b) Indication. The labeling of the product states, under the heading "Use," the following: "For the treatment of pinworms." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M024.50(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) "Abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist consult a doctor."
>
> (2) "If you are pregnant or have liver disease, do not take this product unless directed by a doctor."

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

> (1) Adults, children 12 years of age and over, and children 2 years to under 12 years of age: Oral dosage is a single dose of 5 milligrams of pyrantel base per pound, or 11 milligrams per kilogram, of body weight not to exceed 1 gram. Dosing information should be converted to easily understood directions for the consumer using the following dosage schedule:

Weight	Dosage (taken as a single dose)[1]
Less than 25 pounds or under 2 years old	Do not use unless directed by a doctor.
25 to 37 pounds	125 milligrams.
38 to 62 pounds	250 milligrams.
63 to 87 pounds	375 milligrams.
88 to 112 pounds	500 milligrams.
113 to 137 pounds	625 milligrams.
138 to 162 pounds	750 milligrams.
163 to 187 pounds	875 milligrams.
188 pounds and over	1,000 milligrams.

[1]Depending on the product, the label should state the quantity of drug as a liquid measurement (e.g., teaspoonsful) 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 one 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 § M024.50.

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

§ M024.52 Package inserts for anthelmintic drug products

The labeling of the product contains a consumer package insert that 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 person to person and hygienic procedures to follow to avoid such spreading.

(e) The appropriate labeling information contained in § M024.50.

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

Part D—Professional Use

§ M024.80 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.”