U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M025: Cholecystokinetic 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: 48 FR 27005, June 10, 1983, unless otherwise noted.

Part A—General Provisions

§ M025.1 Scope

An over-the-counter (OTC) 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 OTC Monograph in addition to each of the general conditions established in 21 CFR 330.1.

[48 FR 27005, June 10, 1983]

[1] Final Administrative Order (OTC000019), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

§ M025.3 Definition

As used in this OTC monograph:

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]

Part B—Active Ingredients

§ M025.10 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]

Part C—Labeling

§ M025.50 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 “Uses,” 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 § M025.50(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) 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 before 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 § M025.50.

[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]

Part D—Professional Use

§ M025.80 Professional labeling

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § M025.10: Indication. “For visualization of biliary ducts during cholecystography.”

[54 FR 8321, Feb. 28, 1989]