

U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M002: Antiflatulent Products for Over-the-Counter Human Use (Posted September 20, 2021)¹

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SOURCE: 39 FR 19877, June 4, 1974, unless otherwise noted.

Part A—General Provisions

§ M002.1 Scope

An over-the-counter (OTC) antiflatulent 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 following conditions and each of the general conditions established in 21 CFR 330.1.

¹ Final Administrative Order (OTC000001), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

§ M002.3 Definitions

As used in this OTC monograph:

Antigas. A term that may be used interchangeably with the term antiflatulent. Neither term should be considered as describing the mechanism of action of the active ingredient contained in the product.

[61 FR 8838, Mar. 5, 1996]

Part B—Active Ingredients

§ M002.10 Antiflatulent active ingredients

Simethicone; maximum daily dose 500 mg.

§ M002.15 Combination with non-antiflatulent active ingredients

An antiflatulent may contain any generally recognized as safe and effective antacid ingredient(s) if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Part C—Labeling

§ M002.30 Labeling of antiflatulent 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 an “antiflatulent,” “antigas,” or “antiflatulent (antigas).”

(b) Indications. The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in § M002.30(b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M002.30(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) (Select one of the following: “Alleviates or Relieves”) “the symptoms referred to as gas.”

(2) (Select one of the following: “Alleviates” or “Relieves”) (select one or more of the following: “bloating,” “pressure,” “fullness,” or “stuffed feeling”) “commonly referred to as gas.”

(c) Exemption from the general accidental overdose warning. The labeling for antiflatulent drug products containing simethicone identified in § M002.10 and antacid/antiflatulent combination drug products provided for in § M002.15, containing the active ingredients identified in § M001.11(a), (b), and (d) through (m) of Monograph M001 are exempt from the requirement in 21 CFR 330.1(g) that the labeling bear the general warning statement “In case of accidental overdose, seek professional assistance or contact a poison control center immediately.” The labeling must continue to bear the first part of the general warning in 21 CFR 330.1(g), which states, “Keep this and all drugs out of the reach of children.”

[39 FR 19877, June 4, 1974, as amended at 40 FR 11719, Mar. 13, 1975; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987; 61 FR 8838, Mar. 5, 1996]

Part D—Professional Use

§ M002.31 Antiflatulent active ingredients for professional use

Simethicone; There is no dosage limitation at this time for professional labeling.

§ M002.32 Professional labeling

(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.

(b) Professional labeling for an antiflatulent-antacid combination may contain information allowed for health professionals for antacids and antiflatulents.