

U.S. Food and Drug Administration

**Over-the-Counter (OTC) Monograph M027:
Orally Administered Menstrual Drug Products for Over-the-Counter Human Use
(Posted December 16, 2021)¹**

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SOURCE: 53 FR 46201, Nov. 16, 1988, unless otherwise noted.

Part A—General Provisions

§ M027.1 Scope

An over-the-counter (OTC) menstrual 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.

§ M027.3 Definitions

As used in this OTC monograph:

(a) Diuretic. A drug that increases the excretion of water.

¹ Final Administrative Order (OTC000020), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(b) Menstrual period. The period of time from onset to stoppage of cyclic, physiologic uterine bleeding which (in the absence of pregnancy) normally recurs, usually at approximately 4-week intervals.

(c) Menstruation. The monthly flow of blood from the genital tract of women.

(d) Premenstrual period. The period of time approximately 1 week before onset of menstruation.

(e) Premenstrual syndrome. A recurrent symptom complex that begins during the week prior to menstruation and usually disappears soon after the onset of the menstrual flow. This symptom complex consists predominately of edema; lower abdominal pain (including cramps); breast tenderness; headache; abdominal bloating; fatigue; and feelings of depression, irritability, tension, and anxiety.

Part B—Active Ingredients

§ M027.12 Diuretic active ingredients

The active ingredients of the product consist of the following within the dosage limits established for each ingredient in § M027.52(d):

(a) Acidifying diuretic. Ammonium chloride.

(b) Xanthine diuretics.

(1) Caffeine.

(2) Pamabrom.

§ M027.20 Permitted combinations of active ingredients

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § M027.60.

(a) Any analgesic identified in § M013.10 of OTC Monograph M013 or any combination of analgesics identified in § M013.20(a) of OTC Monograph M013 and any diuretic identified in § M027.12.

(b) Ammonium chloride identified in § M027.12(a) with any one ingredient identified in § M027.12(b).

Part C—Labeling

§ M027.52 Labeling of orally administered menstrual drug products containing diuretic ingredients identified in § M027.12

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "diuretic."

(b) Indications. The labeling of the product states, under the heading "Uses," any of the phrases listed in § M027.52(b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M027.52(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 the relief of temporary water-weight gain, bloating, swelling, and/or full feeling associated with the premenstrual and menstrual periods."

(2) In addition to the indication in § M027.52(b)(1), products containing caffeine identified in § M027.12(b)(1) may also contain the following indication: "For the relief of fatigue associated with the premenstrual and menstrual periods."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing ammonium chloride identified in § M027.12(a).

(i) "Do not use if you have kidney or liver disease."

(ii) "This drug may cause nausea, vomiting, and gastrointestinal distress."

(2) For products containing caffeine identified in § M027.12(b)(1). "The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally rapid heart rate."

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

(1) For products containing ammonium chloride identified in § M027.12(a). Adult oral dosage is 1 gram three times a day for no longer than 6 days.

(2) For products containing caffeine identified in § M027.12(b)(1). Adult oral dosage is 100 to 200 milligrams every 3 to 4 hours while symptoms persist.

(3) For products containing pamabrom identified in § M027.12(b)(2). Adult oral dosage is 50 milligrams four times a day, not to exceed 200 milligrams per day.

§ M027.60 Labeling of permitted combinations of active ingredients

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs.

(b) Indications. The labeling of the product states, under the heading "Uses," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC monographs, unless otherwise stated in § M027.60(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M027.60(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act relating to misbranding and the prohibition in section 301(d) of the FD&C Act 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.

(1) For the permitted combinations identified in § M027.20(a). "For the temporary relief of minor aches and pains and temporary water-weight gain, bloating, swelling, and full feeling associated with the premenstrual and menstrual periods."

(2) For the permitted combinations identified in § M027.20(a) that contain caffeine identified in § M027.12(b)(1) the following indication may be used as an alternative to the one identified in § M027.60(b)(1). "For the temporary relief of minor aches and pains and temporary water-weight gain, bloating, swelling, full feeling, and fatigue associated with the premenstrual and menstrual periods."

(c) Warnings. The labeling of the product states, under the heading "Warning," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC monographs.

(d) Directions. The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC monographs. When the time intervals or age limitations of administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC monograph. For example, an appropriate direction for a tablet containing 25 milligrams pamabrom and 325 mg aspirin would be "Two tablets every 4 to 6 hours not to exceed 8 tablets per day."