

U.S. Food and Drug Administration

**Over-the-Counter (OTC) Monograph M010:
Nighttime Sleep-Aid Drug Products for Over-the-Counter Human Use
(Posted September 20, 2021)¹**

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SOURCE: 54 FR 6826, Feb. 14, 2989, unless otherwise noted.

Part A—General Provisions

§ M010.1 Scope

An over-the-counter nighttime (OTC) sleep-aid 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.

§ M010.3 Definition

As used in this OTC monograph:

Nighttime sleep-aid. A drug that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

¹ Final Administrative Order (OTC000002), 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

§ M010.10 Nighttime sleep-aid active ingredients

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § M010.50(d):

- (a) Diphenhydramine hydrochloride.
- (b) Diphenhydramine citrate.

Part C—Labeling

§ M010.50 Labeling of nighttime sleep-aid 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 "nighttime sleep-aid."

(b) Indications. The labeling of the product states, under the heading "Uses," one or more of the phrases listed in § M010.50(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M010.50(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)).

- (1) ("Helps you" or "Reduces time to") "fall asleep if you have difficulty falling asleep."
- (2) "For relief of occasional sleeplessness."
- (3) "Helps to reduce difficulty falling asleep."

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

- (1) "Do not give to children under 12 years of age."
- (2) "If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness."
- (3) "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

(4) "Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor."

(5) "Do not use [bullet]² with any other product containing diphenhydramine, even one used on skin".

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

(1) For products containing diphenhydramine hydrochloride identified in § M010.10(a). Adults and children 12 years of age and over: Oral dosage is 50 milligrams at bedtime if needed, or as directed by a doctor.

(2) For products containing diphenhydramine citrate identified in § M010.10(b). Adults and children 12 years of age and over: Oral dosage is 76 milligrams at bedtime if needed, or as directed by a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in § M010.50.

[54 FR 6826, Feb. 14, 1989, as amended at 59 FR 16983, Apr. 11, 1994; 67 FR 72559, Dec. 6, 2002]

² See 21 CFR 201.66(b)(4) for definition of bullet symbol.