SLEEP AIDS - LABELLING STANDARD

CATEGORY: Sleep Aids

DESCRIPTION: An over-the-counter drug (tablet, capsule, caplet, powder, or elixir form) that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

MEDICINAL INGREDIENTS and CONCENTRATIONS/DOSAGES:

All finished products as well as ingredients used in the manufacture of the product comply with specifications of a Schedule B pharmacopoeia or equivalent standard

The medicinal ingredients of a product complying with this standard consist of the following when used singly, within the established limits:

A) DIPHENHYDRAMINE HYDROCHLORIDE

25 mg or 50 mg per dosage form

B) DIPHENHYDRAMINE CITRATE

38 mg or 76 mg per dosage form

ADEQUATE DIRECTIONS FOR USE:

Indications:

-the inner and outer label shall show a statement of the indication for use limited to one or more of the following:

1. Helps you (reduces time to) fall asleep if you have difficulty falling asleep;

2. For relief of occasional sleeplessness;

3. Helps to reduce difficulty falling asleep.

4. For the relief of occasional nighttime sleeplessness (insomnia) when due to overwork, tiredness, or fatigue.

Unacceptable Indications:

Any reference to anxiety state, apprehension, worry, concern, fear, and/or tension will be unacceptable for use in association with a sleep aid / sedative product.

Dosage Directions:

For products containing diphenhydramine hydrochloride:

1. Adults and children 12 years of age and older: Take 25 to 50 mg (expressed in terms of dosage form, eg. tablets, capsules, etc., on the label, at bedtime if needed, or as directed by a physician.

2. In some persons, persisting drowsiness may be experienced with a 50 mg dose (two tablets), in which case the medication should be subsequently reduced to 25 mg (one tablet).

For products containing diphenhydramine citrate:

1. Adults and children 12 years of age and older: Take 38 to 76 mg (expressed in terms of dosage form, eg. tablets, capsules, etc., on the label, at bedtime if needed, or as directed by a physician.

2. In some persons, persisting drowsiness may be experienced with a 76 mg dose (two tablets), in which case the medication should be subsequently reduced to 38 mg (one tablet).

WARNINGS

1. For occasional use only. (when not already mentioned in the indication)

2. Do not exceed (increase) recommended dose except on the advice of a physician.

3. If sleeplessness persists continuously for more than 2 weeks, consult your physician. Insomnia may be a symptom of serious underlying medical illness.

4. Do not take this product if you have glaucoma, chronic lung disease, difficulty in urination due to an enlargement of the prostate gland, or if you are pregnant or breastfeeding, unless directed by a physician.

5. Avoid alcoholic beverages while taking this product.

6. If you are presently taking a prescription drug or other medication, do not take this product without first consulting your physician or pharmacist.

7. Not to be used by elderly patients who experience confusion at nighttime. These drugs may produce excitation rather than sedation in the elderly. Therefore they should be avoided in

this age group.

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PACKAGE SIZE LIMITATIONS

Sleep aid drug products containing diphenhydramine hydrochloride are limited to a total content of 1 gram (1 g).

Sleep aid drug products containing diphenhydramine citrate are limited to a total content of 1.5 grams (1.5g).

> **NOTE**: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

REFERENCES

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2. **Remington's Pharmaceutical Sciences**, 18th Edition, Mack Publishing Co., 1990.

3. **United States Federal Register** Vol. 54, No. 29, 1989, pp. 6814-6827, Nighttime Sleep-Aid Drug Products for Over-the-Counter Human Use, Final Monograph; Final Rule.

4. **United States Federal Register** Vol. 47, No. 79, 1982, pp. 17738-17741, Nighttime Sleep-aid Drug Products for Over-the-Counter Human Use, Notice of Enforcement Policy.

5. **American Handbook of Nonprescription Drugs**, 9th Edition, 1990, American Pharmaceutical Association.

6. **Martindale, The Extra Pharmacopoeia**, 29th Edition, 1989, The Pharmaceutical Press.

7. **Canadian Drug Identification Code Book**, 18th Edition, 1992, Health and Welfare Canada.

8. **Drug Facts and Comparisons**, 1989 Edition, Facts and Comparisons Division of J.B. Lippincott Company.

9. **AHFS Drug Information** 1992, American Hospital Formulary Service.

10. **Dorland's Illustrated Medical Dictionary**, 24th Edition, W.B. Saunders Company, Philadelphia, 1965.

11. **Information Letter** No. 779, Health Protection Branch, June 11,

1990.

12. **United States Federal Register** Vol 40, No. 236, 1975, pp. 57292-57329, Over-the-Counter Sleep-Aid Drug Products.

13. **United States Pharmacopoeia USP XXII, National Formulary XVII**, Twenty-second Revision, United States Pharmacopoeial Convention, Inc., 1990.

14. **British Pharmacopoeia**, Volume II, London, 1988.

15. **The Pharmaceutical Codex**, Eleventh Edition, The Pharmaceutical Press, London, 1979.

16. **USP DI**, Drug Information For The Health Care Professional, Volume I, 13th Edition, 1993.

Bureau of Nonprescription Drugs
July 12, 1993

APPENDIX I: FORMULATED PREPARATIONS

FORMULATED PREPARATIONS	U.S.P. XXII (1990)	B.P. (1988)	B.P.C. (1973)
Diphenhydramine Hydrochloride Capsules	X		X
Diphenhydramine Hydrochloride Elixir	X		X