DIMENHYDRINATE LABELLING STANDARD

CATEGORY: Dimenhydrinate

DESCRIPTION: This standard applies to products in tablet, syrup, or suppository form intended to be used for the prevention and treatment of nausea, vomiting or dizziness due to motion sickness

MEDICINAL INGREDIENTS AND CONCENTRATIONS:

All finished product and ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this standard consist of the following ingredients when used singly or in acceptable combinations within the established limits given:

- Dimenhydrinate

ADEQUATE DIRECTIONS FOR USE:

Indications: For the prevention and treatment of nausea, vomiting or dizziness due to motion sickness

Dosage Directions:

1. The following doses of dimenhydrinate are acceptable and should be expressed on the label in number of dosage units (*i.e.* number of tablets, capsules, or suppositories)

2. Dosage should be taken at least 30 minutes, and preferably 1 or 2 hours, **before** tr

ORAL

Adult:	50-100 mg every 4 hours as needed, up to 400 mg in 24 hours
6-12 yrs:	25-50 mg every 6-8 hours as needed, up to 150 mg in 24 hours
2-6 yrs:	12.5-25 mg every 6-8 hours as needed, up to 75 mg in 24 hours
under 2 yrs:	as directed by a physician

RECTAL

Adult:	50-100 mg every 6-8 hours as needed
over 12 yrs:	50 mg every 8-12 hours as needed
8-12 yrs:	25-50 mg every 8-12 hours as needed
6-8 yrs:	12.5-25 mg every 8-12 hours as needed
2-under 6 yrs:	12.5-25 mg
	Dose not to be repeated except on the advice of a physician
under 2 yrs:	as directed by a physician

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NOTE: Where 1/2 of a suppository is indicated in the dosage directions, proper directions for cutting suppositories should be included on the label.

Warnings:

1. May cause drowsiness
2. Avoid alcoholic beverages
3. Do not drive or engage in activities requiring alertness.
4. Do not exceed recommended dosage
5. Prolonged use should be only on the advice of a physician
6. Do not take with other antihistamines, tranquilizers or any other sedating drugs without first consulting your physician
7. 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
8. May cause excitability, especially in children

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.

Product Regulation Division
Bureau of Nonprescription Drugs

REFERENCES:

1. USPDI, Drug Information for the Health Care Professional, Ninth Edition, 1989.
2. Federal Register, Antiemetic Drug Products for OTC Human Use; Volume 52, No. 83, April 30, 1987.
3. Information Letter No. 764, First Report of the Expert AdvisoryCommittee on Nonprescription Cough and Cold Remedies on Antihistamines, Nasal Decongestants and Anticholinergics, August 10, 1989.

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