CYPROHEPTADINE LABELLING STANDARD

CATEGORY: Cyproheptadine

DEFINITION:

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

Cyproheptadine Hydrochloride Tablets, USP XXII (4 mg)
Cyproheptadine Hydrochloride Syrup, USP XXII (2 mg/5 ml)
Cyproheptadine Tablets, BP, 1988

PERMITTED COMBINATIONS:

ADEQUATE DIRECTIONS FOR USE:

Indications:

- helps promote weight gain (appetite stimulant)
- antipruritic/anti-itch
- antihistaminic (H1-receptor)

Dosage Directions:

	Antihistamine	**Appetite Stimulant**
Adults	4 mg every 6-8 hours	4 mg three times daily with meals (max. 6 months)
Children 6-12 yrs.	4 mg every 8-12 hours not exceeding 16 mg in 24 hours	as directed by a physician
2-6 yrs.	2 mg every 8-12 hours not exceeding 8 mg in 24 hours *	as directed by a physician

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*** pending the final recommendations of the EAC on cough and cold products**

Warnings:

1. USE ONLY ON THE ADVICE OF A PHYSICIAN (when promoted for weight gain - C.01.025).

2. May cause drowsiness; avoid alcoholic beverages; do not drive or engage in activities requiring alertness.

3. Never exceed the recommended dosage (I.L. 129).

* 4. Prolonged usage should be only on the advice of a physician (I.L. 129).

CAUTIONS DOCUMENTED IN SEVERAL REFERENCES (no objection to their appearance in label):

* 5. Do not take with other antihistamines, tranquilizers or any other sedating drugs without first consulting your physician.

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

7. May cause excitability, especially in children.

***NOTE** These cautions would not be required on products promoted for weight gain since caution #1 would already appear on the label.
Also, the prostatic hypertrophy and pregnancy/lactation cautions would not apply to products recommended solely for 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.

REFERENCES

1. USP DI, Drug Information for the Health Care Professional, Ninth Edition, 1989.

2. Martindale, The Extra Pharmacopoeia, Twenty-ninth Edition, 1989.

3. United States Pharmacopoeia XXII, 1990

4. British Pharmacopoeia, 1988.

5. Information Letter No. 764, First Report of the Expert Advisory Committee on Nonprescription Cough and Cold Remedies on Antihistamines, Nasal Decongestants and Anticholinergics, August 10, 1989.

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Bureau of Nonprescription Drugs
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