POISON TREATMENT DRUG PRODUCTS - LABELLING STANDARD

MEDICINAL INGREDIENTS:

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:

- Ipecac Syrup
- Activated Charcoal

NOTE: In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

IPECAC SYRUP:

DEFINITION: an emetic used to induce vomiting in overdose and in certain poisonings (Ipecac fluid extract and Ipecac tincture are not used)

ADEQUATE DIRECTIONS FOR USE:

Indications:

- for emergency use to cause vomiting of swallowed poisons
- emetic

Dosage Directions:

- **Adults and Children 12 years of age and over:** 2 tablespoonfuls (30 ml) followed by 1 or 2 glasses of water or other clear liquid or as directed by a health professional

- **Children 1 to 12 years of age;** 1 tablespoonful (15 ml) followed by 1 or 2 glasses of water or other clear liquid or as directed by a health professional

- **Children 6 months to 1 year:** 1 teaspoonful (5 ml) followed by 1/2 to 1 glass of water or other clear liquid or as directed by a health professional

- **Children under 6 months:** Use only on the advice of a

health professional

1. If vomiting does not occur within 30 minutes, repeat dose.
2. Keep patient active and moving.
3. Save the container of poison.

Warnings:

1. Do not give to persons who are not fully conscious.

2. Do not administer milk with this product.

3. Do not use if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, paint thinner, cleansing fluid or furniture polish have been ingested.

4. Do not give activated charcoal until after the patient has vomited.

ACTIVATED CHARCOAL:

DEFINITION: is a poison adsorbent as it adsorbs the toxic substance ingested, thus inhibiting gastrointestinal absorption

ADEQUATE DIRECTIONS FOR USE:

Indications:

- poison adsorbent, or emergency poison adsorbent, or for emergency use to adsorb swallowed poisons, or first aid poison adsorbent

Dosage Directions:

- **Oral Dosage:** 20 to 30 grams of activated charcoal in a minimum of 8 ounces of liquid or as directed by a health professional

1. Repeat dose immediately, if possible.
2. Keep patient active and moving.
3. Save the container of poison.

Warnings:

1. Do not give to persons who are not fully conscious.

2. Do not give activated charcoal until after the patient has vomited, unless directed by a health professional.

3. Do not use this product, unless directed by a health professional, if turpentine, corrosive, such as alkalies (lye) and strong acids, or petroleum distillate such as kerosene, gasoline, paint thinner, cleansing fluid or furniture polish have been ingested.

Warnings: **(Both Ipecac and Activated Charcoal)**

1. If previous attempts to contact a poison control centre, emergency medical facility or health professional were unsuccessful, continue trying.

2. If possible, call a poison control centre, emergency medical facility or health professional for help before using this product.

3. If help cannot be reached quickly, follow the directions.

4. As soon as you buy this product read the warnings and direction. Insert emergency phone number(s) in space provided on label.

NOTE: A space must be provided on the label for writing in the phone number of the appropriate poison control centre or health professional.

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: Federal Register, January 15, 1985

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Bureau of Nonprescription Drugs
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