

SYRUP CHILDREN

COMPOSITION

Exclipients: ascorbic acid, ipecacuanha compound syrup, tolu balm syrup, propyl gallate, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), orange flavouring, mandarin flavouring, strawberry flavouring, vanillin, saccharose solution, concentrated sodium hydroxide solution, purified water, q.s.p. 100 ml. Alcohol content: 1.5% - bottle of 125 ml of syrup,

THERAPEUTIC INDICATIONS

This medicine contains an antitussive agent. It is recommended for use to soothe dry or irritative cough in children over 13 kg in weight (i.e. approximately 30 months and above).

CONTRA-INDICATIONS

This medicine MUST NOT BE USED in the following situations:

■ Past history of allergy to any of the constituents ■ Dry cough in asthmatic patients ■ Patients with respiratory insufficiency ■ Mothers who are breast-feeding ■ Children less than 30 months of age.

This medicine MUST NOT NORMALLY BE TAKEN in association with alcohol.

WARNINGS

Productive cough should not be treated with this medicine. In this situation, cough is a natural defence mechanism to remove bronchial secretions. Seek medical advice if the cough becomes productive or is associated with congestion, sputum or fever, It is essential that patients with chronic diseases (long term) of the bronchi or lungs associated with productive cough seek medical advice,

PRECAUTIONS FOR USE

INFORM YOUR DOCTOR if you are suffering from long term liver disease.

You should be aware that this product contains saccharose (0.55 g per ml) if you are diabetic or following a reduced carbohydrate diet (low sugar). You should not use this product in association with medicines which fluidify bronchial secretions (expectorants, mucolytic agents).

THERAPEUTIC INTERACTIONS AND OTHER INTERACTIONS

This medicine contains an antitussive agent, codeine. Other medicines may contain codeine or a different antitussive agent. These should not be used in association, in order to avoid exceeding the maximum recommended doses (see Posology and Method of Administration). IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, particularly alcohol, YOU SHOULD ALWAYS REPORT ANY OTHER TREATMENT YOU ARE TAKING TO YOUR DOCTOR OR PHARMACIST.

PREGNANCY - BREAST-FEEDING

- Pregnancy: This medicine should only be used during pregnancy when necessary. If you discover that you have become pregnant during treatment, you should inform your doctor as only your doctor can judge whether you should continue treatment
- Breast-feeding: This medicine passes into breast milk.

Administration of excessively high doses of codeine to women who are breast-feeding may cause respiratory gaps or reduced tone in the infant. This medicine is contra indicated if you are breast-feeding.

AS A GENERAL MEASURE, YOU SHOULD ALWAY'S ASK YOUR DOCTOR'S OR PHARMACIST'S ADVICE BEFORE USING A MEDICINE IF YOU ARE PREGNANT OR BREAST-FEEDING

DRIVERS AND MACHINE OPERATORS

Attention is drawn to vehicle drivers and machine operators that use of this medicine may cause drowsiness. This effect is increased by consumption of alcoholic beverages. Treatment should preferably be started in the evening.

SPORTSMEN AND WOMEN: Note that this medicine contains a substance which may produce a positive reaction in an anti-doping test.

DOSAGE AND ADMINISTRATION

For oral use - ONLY FOR USE IN CHILDREN OVER 13 KG IN WEIGHT (i.e. APPROXIMATELY 30 MONTHS OR OVER).

Do not increase doses above recommended limits if the product is not effective. Do not take in conjunction with any other antitussive agents; in this situation consult your doctor. Use the graduated dose measure provided. Doses should be determined according to the weight of your child, i.e.:

- children from 13 to 20 kg in weight (approximately 30 months to 6 years old): 1 x 2.5 ml graduated measure per dose, repeated

after 6 hours if necessary, not exceeding 4 doses per day.

- children from 20 to 25 kg in weight (approximately 6 to 8 years old): 1 x 5 ml graduated measure per dose, repeated after 6 hours if necessary, not exceeding 4 doses per day.

- children from 25 to 40 kg in weight (approximately 8 to 12 years old): 1 x 10 ml graduated measure per dose, repeated after

6 hours if necessary, not exceeding 4 doses per day.

- children from 40 to 50 kg in weight (approximately 12 to 15 years old): 1 x 15 ml graduated measure per dose, repeated after

6 hours if necessary, not exceeding 4 doses per day.

Consult your doctor in order that doses may be adjusted in patients with hepatic insufficiency.

Approximate ages corresponding to weights are given as an indication only. Doses should be taken a minimum of 6 hours apart. Treatment must only be short term (for a few days), CONSULT a doctor in the event of overdose.

SIDE EFFECTS:

AS APPLIES TO ANY ACTIVE SUBSTANCE, THIS MEDICINE MAY CAUSE EFFECTS OF VARYING SEVERITY IN CERTAIN INDIVIDUALS: The following may occur; constination, drowsiness, dizziness, nausea, vomiting, Rarely; respiratory problems, skin rashes,

Juillet 2007

008280 / V 87168-08