SCHEDULING STATUS: S2

PROPRIETARY NAME: **ADCO-ALCOPHYLLIN**

(AND DOSAGE FORM) **(MIXTURE)**

COMPOSITION:

Each 5 ml contains:

Theophylline anhydrous…… 26,667 mg

Preservatives:

Methylparaben……. 0,1 % *m/v*

Propylparaben…….. 0,015 % *m/v*

Alcohol……..0.5 % *v/v*

Contains sugar: Sucrose…..2,94 g

Other inactive ingredients: colour raspberry red, colour red, flavour raspberry, and purified water.

CATEGORY AND CLASS:

A 10.2 Medicines acting on respiratory system - Bronchodilators

PHARMACOLOGICAL ACTION:

Bronchodilator.

INDICATIONS:

Bronchial asthma and chronic obstructive pulmonary disease.

CONTRAINDICATIONS:

Hypersensitivity to theophylline.

WARNINGS AND SPECIAL PRECAUTIONS:

Administer with caution to patients with peptic ulceration, hyperthyroidism, hypertension, cardiac

arrhythmias or other cardiovascular disease as these conditions may be exacerbated.

Theophylline should be given with caution to patients with congestive heart failure, hepatic dysfunction or chronic alcoholism, acute febrile illness, severe hypoxia, cor pulmonale, acute pulmonary oedema, or other chronic lung disease and to neonates and the elderly, since in all of these circumstances theophylline clearance may be decreased, resulting in increases in serum-theophylline concentrations and serum half-life.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take ADCO-ALCOPHYLLIN. Sucrose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

The bronchodilator and toxic effects of theophylline may be enhanced by sympathomimetics and by administration with other xanthines. Interaction with allopurinol, cimetidine, influenza vaccine, propranolol, erythromycin and some other macrolides may result in decreased hepatic theophylline clearance and increased serum half-life, necessitating dosage reduction. Phenytoin and some other anticonvulsants and cigarette smoking may increase theophylline clearance, necessitating an increase in dose or dosing frequency.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 3 to 6 medicine measures three times a day or as directed.

Children 2 to 6 years: ½ to 2 medicine measures not more often than 8 hourly.

7 to 12 years: 2 to 3 medicine measures not more often than 8 hourly.

Administer with care – (see **'WARNINGS AND SPECIAL PRECAUTIONS'**).

SIDE EFFECTS:

Theophylline may cause nausea, vomiting, abdominal pain, gastric irritation, gastrointestinal bleeding, insomnia, headache, anxiety, restlessness, vertigo and palpitations and central nervous system stimulation.

Severe overdosage or idiosyncrasy may lead to maniacal behaviour, diuresis and repeated vomiting with extreme thirst, tremor, delirium, hyperthermia, tachycardia, tachypnoea, electrolyte disturbances, convulsions and death. Convulsions may not be preceded by milder symptoms of toxicity.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms as under **'SIDE EFFECTS'**.

Overdosage in children can be dangerous as absorption is unpredictable.

Treatment is symptomatic and supportive.

IDENTIFICATION :

Clear, red, syrupy liquid with an odour of raspberry.

PRESENTATION :

Containers holding 100 ml, 200 ml and 2,5 L.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in airtight containers. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G721 (Act 101/1965)

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