SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

RESMED D.P.H. EXPECT (SOLUTION)

COMPOSITION: Each 5 ml contains:

Diphenhydramine Hydrochloride 12,5 mg

Ammonium Chloride 125,0 mg

Sodium Citrate 50,0 mg

Preserved with Methyl Hydroxybenzoate 0,2% m/v

Contains 4,84% v/v Alcohol

PHARMACOLOGICAL CLASSIFICATION: Category A

Classification 10.1 Antitussives & Expectorants

PHARMACOLOGICAL ACTION: It alleviates cough.

INDICATIONS: For the alleviation of cough.

CONTRA-INDICATIONS: Hypersensitivity to any of the ingredients. Contra-indicated in the presence of impaired renal or hepatic function.

WARNINGS: Resmed D.P.H. Expect may enhance the effects of central nervous system depressants. Use of this medicine leads to drowsiness, which is aggravated by the simultaneous intake of alcohol. Patients should not operate hazardous machinery or drive motor vehicles when under medication.

DOSAGE & DIRECTIONS FOR USE:

Adults: 10 ml four-hourly, or as necessary, with meals.

SIDE EFFECTS & SPECIAL PRECAUTIONS:

Side effects with antihistamines vary in incidence and severity with each patient. The following side effects have been reported for drugs in the antihistamine class: dizziness, lassitude, hypotension, muscular weakness and incoordination, nausea, vomiting, diarrhoea or constipation, colic and epigastric pain. Antihistamines may also produce headache, hallucinations, blurred vision, tinnitus, elation or depression, irritability, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and weakness of the hands. Large doses of antihistamines may precipitate fits in epileptics. Blood dyscrasias, including agranulocytosis, haemolytic anaemia and thrombocytopenic purpura, though rare, have been reported. As with all drugs, care should be taken when administering this preparation during the first trimester of pregnancy. Preparations containing sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy. Menthol may give rises to hypersensitivity reactions including contact dermatitis. In young children spasm of glottis may occur.

KNOWN SYMPTOMS OF OVERDOSAGE & PARTICULARS OF ITS TREATMENT:

In the small child, the dominant effect is excitement including hallucinations, ataxia, incoordination, athetosis and convulsions. Fixed, dilated pupils with a flushed face and fever are common. In the adult, fever and flushing are not usually in evidence. The phase of excitement leading to convulsions and postictal depression is not uncommonly preceded by drowsiness and coma. Large doses of ammonium chloride produces nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, mental confusion, hyperchloraemia, acidosis and hypokalaemia. Sodium retention leads to accumulation of fluid with cerebral oedema and peripheral and pulmonary oedema. Symptoms of hypernatraemia may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, oliguria, dizziness, headache, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrests. Treatment is symptomatic and supportive.

CONDITIONS OF REGISTRATION:

IDENTIFICATION: A dark brown liquid with the characteristic smell of chloroform and menthol.

PRESENTATION: In 50 ml, 100 ml, 200 ml & 2,5 l plastic amber containers.

STORAGE INSTRUCTIONS: Store in a cool (below 25^0C) dark place and out of the reach of children.

REGISTRATION NUMBER: T/10.1/203

NAME AND BUSINESS ADDRESS OF APPLICANT:

Resmed Healthcare

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DATE OF PUBLICATION OF THIS PACKAGE INSERT: 28/10/1985