EXPECTALIN

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

Expectalin (liquid)

COMPOSITION:

Each 5 ml contains:

Diphenhydramine hydrochloride	12,5 mg
Ammonium chloride	125,0 mg
Preserved with Sodium Benzoate	0,5 % m/v
Sugar free	
Alcohol free	

PHARMACOLOGICAL CLASSIFICATION:

A: 10.1 Antitussives and expectorants.

INDICATIONS:

Expectalin is indicated for the relief of cough.

CONTRA-INDICATIONS:

Known sensitivity to any of the ingredients. Diphenhydramine hydrochloride should not be used with monoamine oxidase inhibitors, or within 14 days of stopping monoamine oxidase inhibitor treatment.

Contra-indicated during acute asthmatic attacks, and in patients with impaired hepatic or renal function.

Safety in pregnancy and lactation has not been established. Should not be used in infants under the age of 2 years.

WARNING:

This medicine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights as impaired decision making could lead to accidents.

DOSAGE AND DIRECTIONS FOR USE:

A maximum of four doses per day should not be exceeded.

Children: 2 to 6 years: 2,5 ml every 4 hours.

7 to 12 years: 2,5 - 5 ml every 4 hours

Adults: One to two 5 ml medicine measures every 3 - 4 hours.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Diphenhydramine hydrochloride:

The most common side-effect of diphenhydramine hydrochloride is sedation which can vary from slight drowsiness to deep sleep, and includes lassitude, dizziness and inco-ordination. Other side-effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, and epigastric pain. Antimuscarinic effects include blurred vision, difficulty in micturition, dysuria, dryness of the mouth, and tightness of the chest. Other central effects include hypotension, muscular weakness, tinnitus, euphoria, and headache.

In infants and children it may act as a cerebral stimulant. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors and convulsions.

Large doses may precipitate fits in epileptics. Deepening coma, extrapyramidal effects and photosensitization of the skin may occur.

Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects.

Allergic reactions and anaphylaxis may occur. Blood dyscrasias including agranulocytosis, leucopenia and haemolytic anaemia may occur.

Diphenhydramine has been reported to cause thrombocytopenia

The positive results of skin tests may be suppressed.

Diphenhydramine hydrochloride has anticholinergic properties and should be used with care in conditions such as glaucoma, urinary retention and prostatic hypertrophy. Diphenhydramine hydrochloride should be used with caution in patients with liver impairment or cardiovascular disease.

The anticholinergic effects of atropine and tricyclic antidepressants may be enhanced by diphenhydramine hydrochloride. MAO inhibitors may enhance the anticholinergic effects.

Diphenhydramine hydrochloride may mask the warning symptoms of damage caused by ototoxic medicines such as aminoglycoside antibiotics, and may affect the metabolism of other medicines in the liver. It may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

Ammonium chloride:

Large doses of ammonium chloride may cause nausea, vomiting, drowsiness, thirst, headache, hyperventilation, profound acidosis and hypokalaemia. Excessive doses may give rise to hepatic encephalopathy.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Diphenhydramine hydrochloride:

Overdosage may be fatal especially in infants and children.

In infants & children CNS stimulations predominates over CNS depression causing ataxia, excitement, tremors, psychoses, hallucinations and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow. In adults, CNS depression with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular colapse.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, light brown liquid with a raspberry odour and taste.

PRESENTATION:

Bottles containing 100 ml and 200 ml, with a plastic measuring cup.

STORAGE INSTRUCTIONS:

Store in a cool place (at or below 25 °C).

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

28/10.1/0248.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

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