BENYLIN WITH CODEINE

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

Benylin with Codeine (syrup)

COMPOSITION:

Each 5 ml contains:

Diphenhydramine hydrochloride	12,5 mg
Codeine phosphate	10,0 mg
Ammonium chloride	125,0 mg
Alcohol	5 % v/v
Sugar	1,0 g
Glucose	2,3 ml
Preserved with Sodium Benzoate	0,2 % m/v

Contains sugar

Excipients:

L-Menthol, sodium citrate hydrous, denatured alcohol menthol, sugar, glucose, glycerine, citric acid hydrous, saccharin sodium, sodium cyclamate, Ponceau 4R, caramel clarkes, sodium benzoate, raspberry flavour, special flavour and water purified.

PHARMACOLOGICAL CLASSIFICATION:

A: 10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION:

Diphenhydramine hydrochloride is an antihistaminic and, by its atropine-like action, relieves cough. Codeine is a centrally acting cough suppressant.

INDICATIONS:

Benylin with Codeine is indicated for the relief of cough.

CONTRA-INDICATIONS:

Known hypersensitivity to any of the ingredients. Neither diphenhydramine hydrochloride nor codeine phosphate should be used with monoamine oxidase inhibitors or within 14 days of stopping treatment with monoamine oxidase inhibitors.

Contra-indicated during acute asthma attacks, in the presence of acute alcoholism, head injuries and raised intracranial pressure, and in patients with impaired hepatic or renal function.

Should not be used in children under the age of 6 years.

WARNINGS and SPECIAL PRECAUTIONS:

The use of 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.

Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependency and addiction.

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.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with obstructive bowel disorders and in patients with myasthenia gravis. The dosage should be reduced in elderly and debilitated patients.

The prolonged use of high doses of codeine has produced dependence of the morphine type.

INTERACTIONS:

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.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, phenothiazines and tricyclic antidepressants.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

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

Adults: One to two 5 ml medicine measures (5 ml – 10 ml) every 4 hours.

Children 6 to 12 years: A half to one medicine measure (2,5 ml - 5 ml) every 4 hours.

DO NOT USE FOR LONGER THAN 3 DAYS.

SIDE-EFFECTS:

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 photosensitivity 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.

Codeine phosphate:

The most common side-effects are nausea, vomiting, constipation, drowsiness and confusion. Dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension,

hypothermia, restlessness, changes of mood, miosis and raised intracranial pressure also occur. Micturition may be difficult and there may be ureteric or biliary spasm. There is also an antidiuretic effect.

Due to the histamine-releasing effect allergic reactions such as urticaria, pruritus and itching of the nose occur in some individuals.

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 collapse.

Codeine phosphate:

Produces central stimulation with exhilaration and, in children, convulsions, followed by vomiting, drowsiness, respiratory depression and cyanosis, and coma.

<u>Treatment</u>

Naloxone hydrochloride is used to counteract the respiratory depression and coma produced by excessive doses of codeine. A dose of 0,4 to 2 mg is given intravenously, repeated at intervals of 2 to 3 minutes if necessary, up to 10 mg. In children, an initial dose of 10 µg per kg

body weight may be given intravenously followed, if necessary, by a larger dose of 100 µg per kg.

Further treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, dark brown syrup having a raspberry odour and taste.

PRESENTATION:

Bottles containing 100 ml with a plastic measuring cup.

STORAGE INSTRUCTIONS:

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

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G830 (Act 101/1965)

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

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

7945

South Africa

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