SCHEDULING STATUS: S2

PROPRIETARY NAME: **BRONCLEER WITH CODEINE COUGH SYRUP**

(AND DOSAGE FORM) **(SYRUP)**

COMPOSITION:

Each 5 ml contains:

Codeine phosphate	10 mg
Diphenhydramine HCl	12,5 mg
Ammonium chloride	125 mg
Sodium citrate	50 mg
Preservative:	
Nipastat	0,02 % *m/v*
Alcohol 96.5 %	0,5 % *v/v*
Contains sugar:	
Sucrose	4,038 g

Excipients: acid citric monohydrate**,** essence raspberry No. 1, levomenthol, liq. sacch. UST 50 % solution

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Medicines acting on respiratory system - Antitussives and expectorants

INDICATIONS:

For the alleviation of cough.

CONTRAINDICATIONS:

Sensitivity to the components. Patients with impaired renal or hepatic function.

Patients with respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

Do not use in children under 2 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

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

The use of this medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned against performing potentially hazardous tasks where loss of concentration may lead to accidents.

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 inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

Larger doses produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur in children.

Large doses of diphenhydramine HCl may precipitate fits in epileptics.

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

Diphenhydramine HCl should be used with care in conditions that can be exacerbated or otherwise adversely affected by atropine, such as glaucoma and prostatic hypertrophy.

Sodium citrate should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema.

INTERACTIONS:

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

Diphenhydramine HCl may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilizers. The effects

of anticholinergic drugs such as atropine and tricyclic antidepressants may be enhanced by concomitant administration.

PREGNANCY AND LACTATION:

Sodium citrate should be used with caution in toxaemia of pregnancy.

DOSAGE AND DIRECTIONS FOR USE:

Children 2 to 6 years:	(2,5 ml) half a medicine measure every four hours.
Children 6 to 12 years:	(5 ml) one medicine measure every four hours.
Adults:	One to two 5 ml medicine measures every four hours.

Not recommended for children under 2 years of age.

A maximum daily dose not exceeding 80 milligrams,

Codeine: Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependence and addiction (see **WARNINGS AND SPECIAL PRECAUTIONS)**.

SIDE EFFECTS:

Codeine may cause vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis. Micturition may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur.

Diphenhydramine HCl may give rise to the following side effects: sedation, varying from slight drowsiness to deep sleep, and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and incoordination.

Other side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, and epigastric pain.

Diphenhydramine HCl may also cause headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest, and tingling, heaviness and weakness of the hands.

Symptoms of cerebral stimulation may arise in some adults and they include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Ammonium chloride: large doses may cause nausea, vomiting, thirst, headache, hyperventilation, and progressive drowsiness, and lead to profound acidosis and hypokalaemia.

Sodium citrate: hypernatraemia may occur and the symptoms include restlessness, weakness, thirst, reduced salivation and tear production, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms as under **'SIDE EFFECTS'**. In addition symptoms of codeine overdosage, are the development of coma, respiratory depression, cyanosis and hypotension together with pin-point non-reactive pupils.

Symptoms of overdosage in infants and children may include convulsions and hyperpyrexia.

Treatment is supportive and symptomatic.

IDENTIFICATION:

A brown syrup with a raspberry odour.

PRESENTATION:

Glass bottles of 100 ml and 100 ml in plastic bottles.

STORAGE INSTRUCTIONS:

Keep bottle tightly closed. Protected from light. Store in a cool place (at or below 25 °C)

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

G/10.1/1112

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

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