SCHEDULING STATUS: S2

PROPRIETARY NAME: TUSSITOT

(AND DOSAGE FORM) (SYRUP)

COMPOSITION:

Each 5 ml contains:

Codeine phosphate 2,5 mg

Diphenhydramine hydrochloride 7,0 mg

Ammonium chloride 68,5 mg

Sodium citrate 28,0 mg

Preservative: Nipastat 1,000 mg

Contains sugar:

Sucrose refined 4166.65 mg

Inactive ingredients: Caramel clarks, chloroform, chloroform spirit, L-menthol, nipastat, Raspberry Essence No.1 (Flavourant) and sucrose refined.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Codeine phosphate is an opioid. It has an analgesic and cough suppressant action.

Diphenhydramine hydrochloride is an antihistamine. It has sedative and anticholinergic properties.

Ammonium chloride: Is used as an expectorant.

INDICATIONS:

For alleviation of cough.

CONTRAINDICATIONS:

Known hypersensitivity to any of the ingredients.

Should not be used during pregnancy and lactation.

Do not use in children under 2 years of age.

Codeine phosphate: Is contraindicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease, in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised. Codeine is contraindicated in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment.

Diphenhydramine hydrochloride: The antihistamines are contraindicated in patients with acute porphyria and in premature infants or neonates

Ammonium chloride: Should not be given to patients with impaired renal or hepatic functions, advanced arteriosclerosis or dehydration.

WARNINGS AND SPECIAL PRECAUTIONS:

TUSSITOT may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

Large doses may precipitate seizures in epileptics.

Codeine

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

Codeine Phosphate should be given with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy, myasthenia gravis, shock or inflammatory or obstructive bowel disorders. 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.

Diphenhydramine hydrochloride should be used with caution in patients with epilepsy or severe cardiovascular disorders and in conditions such as closed angle glaucoma, urinary retention, prostatic hypertrophy or pyloroduodenal obstruction.

Sodium salt containing preparations should be used cautiously in patients with congestive heart failure, hypertension, impaired renal function, cirrhosis of the liver, or pre-eclampsia, peripheral or pulmonary oedema also in patients receiving corticosteroids.

Effects on ability to drive and use machinery:

This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol and other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

INTERACTIONS:

TUSSITOT may enhance the sedative effects of central nervous system depressants including alcohol, anaesthetics, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, tricyclic antidepressants and neuroleptics.

Diphenhydramine hydrochloride: Incompatibility has been reported with amphotericin, cephalothin sodium, hydrocortisone sodium succinate, and solutions of alkalis or strong acids.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established

DOSAGE AND DIRECTIONS FOR USE:

1 medicine measure = 5 ml.

Take 4 hourly as required.

2 to 6 years: 1 medicine measure.

6 to 12 years: 2 medicine measures.

Over 12 years: 3 medicine measures.

Not for use in children under 2 years of age (See CONTRAINDICATIONS).

SIDE EFFECTS:

Codeine phosphate: May cause the following and the frequencies are unknown:

Eye disorders	Miosis
Ear and labyrinth disorders	Vertigo
Psychiatric disorders	Confusion, changes of mood, restlessness
Nervous system disorders	Drowsiness, sweating

Cardiac disorders	Palpitations, bradycardia, arrhythmias
Vascular Disorders	orthostatic hypotension; facial flushing, hypothermia
Gastrointestinal disorders	Constipation, nausea, vomiting and dry mouth
General disorders and administration site conditions	Difficulty in micturition; ureteric or biliary spasm

Diphenhydramine hydrochloride: May give rise to the following side effects:

System Organ Class	**Adverse Effect**	**Frequency**
Immune system disorders	Hypersensitivity reactions (cross-sensitivity to related drugs may occur)	Unknown
Psychiatric disorders	Sedation, drowsiness, lassitude.	
Nervous system disorders	Dizziness, inco-ordination; CNS stimulation (especially in children) with insomnia, nervousness, euphoria, irritability, tremors, nightmares, hallucinations and convulsions.	Unknown
Cardiac disorders	Transient bradycardia followed by tachycardia with palpitations and arrhythmias.	Unknown
Eye Disorders	Blurred vision	Unknown
Respiratory, thoracic and mediastinal disorders	Thickened respiratory tract secretions, tightness of the chest.	Unknown
Gastrointestinal disorders	Reduction in tone and motility of the gastrointestinal tract resulting in constipation and increased gastric reflux. Nausea, vomiting, diarrhoea, gastric pain.	Unknown
General disorders and administration site conditions	Urinary difficulty and retention.	Unknown

Ammonium chloride: Is irritant to the gastric mucosa and may produce nausea and vomiting particularly in large doses. Ammonium chloride can also produce a transient diuresis and mild acidosis.

Sodium citrate:

The following side-effects may occur and the frequencies are unknown:

Eye disorders	Reduced lacrimation
Psychiatric disorders	Restlessness, irritability
Nervous system disorders	Headache, dizziness, drowsiness, weakness, muscular twitching and convulsions.
Cardiac disorders	Tachycardia, hypertension
Vascular Disorders	Sweating
Gastrointestinal disorders	Stomach cramps, flatulence, constipation, nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation.
Respiratory, thoracic and mediastinal disorders	Respiratory arrest, pulmonary oedema
General disorders and administration site conditions	Fever, peripheral oedema

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Codeine phosphate: Symptoms of overdosage include respiratory depression, hypotension, excitement and convulsions may occur especially in children.

The triad of coma, pinpoint pupils and respiratory depression are indicative of overdosage.

Diphenhydramine hydrochloride: In large doses may precipitate fits in epileptics.

Children: CNS stimulation predominates over CNS depression, causing ataxia, excitement tremors, hyperpyrexia, hallucinations and convulsions.

Adults: CNS depression is more common with drowsiness, convulsions and coma.

Ammonium chloride: Large doses may cause a profound acidosis and hypokalaemia which should be treated symptomatically.

Sodium citrate: Retention of sodium leads to the oedema, affecting cerebral, peripheral and pulmonary circulatory systems. Excessive administration of bicarbonate may lead to metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include shortness of breath and muscle weakness. Seizures may be exacerbated or precipitated in epileptic patients.

If vomiting has not occurred spontaneously, the patient should be induced to vomit or empty the stomach by gastric lavage. The patient should be kept quiet to minimise excitation which can occur particularly in children. Other treatment is symptomatic and supportive and may include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids. Respiratory depression should
be treated with assisted respiration. In severe hypotension, the circulation should be maintained with infusion of plasma or suitable electrolyte solutions. Metabolic alkalosis should be treated by correcting fluid and electrolyte balance.

IDENTIFICATION:

A clear, brown, viscous liquid. Odour and taste of menthol and raspberry.

PRESENTATION:

100 ml bottle.

STORAGE INSTRUCTIONS:

Store in a cool place at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G999 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

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