SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **CEPACOL® SORE THROAT AND COUGH RELIEF DISCS**

(AND DOSAGE FORM) **(LOZENGE)**

COMPOSITION:

Each cough disc contains:

Dextromethorphan hydrobromide	4,98 mg
Cetylpyridinium chloride	0,50 mg
Benzocaine	1,25 mg

in a candy base

Contains sugar

Sucrose	1,67 g
Anhydrous liquid glucose	0,72 g

Contains sweetener:

Sodium Saccharin	1,75 mg

List of excipients: Levomenthol, mint oil, anethole, sodium chloride, anhydrous caramel, sodium carbonate, purified water.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Dextromethorphan hydrobromide is a non-narcotic antitussive agent which is believed to inhibit the cough reflex by acting on the cough centre in the medulla. Clinical studies in patients with both acute and chronic cough have demonstrated significant cough suppression. It has a relatively long antitussive action lasting from 6 to 8 hours.

Benzocaine: Has a mild local anaesthetic action which helps to alleviate sore or irritated throats.
Cetylpyridinium chloride: Laboratory studies show that cetylpyridinium chloride has a marked bactericidal action against a wide range of bacteria and is effective against pathogenic organisms which are associated with sore throats due to colds. It also has antifungal properties. By lowering surface tension (detergent action) it spreads over the oral and pharyngeal mucosa to loosen and disperse bacterial laden mucous in the mouth and throat.

INDICATIONS:

CEPACOL SORE THROAT AND COUGH RELIEF DISCS provide rapid and continuous relief of coughs due to colds. CEPACOL SORE THROAT AND COUGH RELIEF DISCS alleviate and soothe sore throats irritated by continual coughing and inflammation caused by colds and other throat irritations associated with dust, allergy, smoke, etc.

CONTRA-INDICATIONS:

Known idiosyncrasy or hypersensitivity to dextromethorphan hydrobromide, cetylpyridinium chloride, benzocaine or related substances. Benzocaine is contraindicated in patients with low plasma cholinesterase concentrations or in those receiving anticholinesterases.

WARNINGS AND SPECIAL PRECAUTIONS:

Severe sore throats or sore throat accompanied by high fever or headache or nausea and vomiting, or any sore throat persisting for more than two days, may be serious. In such cases, consult a doctor.
Dextromethorphan should not be given to patients with or at risk of developing respiratory failure.
Administration of dextromethorphan to patients receiving monoamine oxidase inhibitors may produce severe reactions; hyperpyrexia and fatalities have been reported.
Dextromethorphan has been subject to abuse but there does not appear to be any evidence of dependence of the morphine type.
CEPACOL SORE THROAT AND COUGH RELIEF DISCS may not to be used in children under the age of 2 years.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take CEPACOL SORE THROAT AND COUGH RELIEF DISCS.

Contains Sucrose and Anhydrous liquid glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

DOSAGE AND DIRECTIONS FOR USE:

Repeat every three hours as needed.

Adults and children over 12 years old: Dissolve 2 cough discs in the mouth one at a time. Children 6 - 12 years old: Dissolve 1 cough disc in the mouth.

Do not exceed the recommended dose.

Do not use in the children under six years of age.

SIDE EFFECTS:

Dextromethorphan hydrobromide: Gastrointestinal disturbances, drowsiness, dizziness and excitation have very occasionally been associated with dextromethorphan therapy.

Benzocaine: Systemic adverse effects may occur with benzocaine, as results of the absorption of large amounts through mucous membranes or damaged skin or from highly vascular areas. Excitation of the central nervous system (CNS) may be manifested by yawning, restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nystagmus, nausea and vomiting, muscle twitching and tremors and convulsions. Numbness of the tongue and perioral regions is an early sign of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma.

There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia, arrythmias and cardiac arrest may occur.

Idiosyncratic reactions have been reported. Allergic reactions may occur. Benzocaine should be given cautiously to the elderly, and to children, to patients with epilepsy, impaired cardiac conduction or respiratory function, shock, or with liver damage; patients with myasthenia gravis are particularly sensitive to the effects of local anaesthetics.

When used in the mouth or throat, local anaesthetics may impair swallowing and increase the risk of aspiration.

CEPACOL SORE THROAT AND COUGH RELIEF DISCS may cause methaemoglobinaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may cause nausea and vomiting. It has depolarising muscle relaxant properties and toxic symptoms include·dyspnoea and cyanosis due to paralysis of the respiratory muscle, possibly leading to asphyxia. Depression of the CNS with convulsions, hypotension and coma may occur.

Dextromethorphan overdosage may cause excitation, confusion and respiratory depression.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Round, dark brown hard candy lozenge embossed with "+" on both sides.

PRESENTATION:

Blister pack of 16 lozenges.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light and moisture. **KEEP OUT OF REACH OF CHILDREN.**

REGISTRATION NUMBER:

B/10.1/163

Botswana	S3	B9316105
Namibia	NS1	90/10.1/00107

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