SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

RELIEF-COFF EXPECTORANT, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Diphenhydramine hydrochloride	14 mg
Ammonium chloride	136 mg
Sodium citrate	56 mg

Preservative:

Sodium methyl paraben	0,125 % *m/v*

Sugar free.

Contains sweeteners as saccharin sodium 7,50 mg per 5 ml.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution.

A clear, brown solution, free from visible particles, with an odour characteristic of menthol.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The alleviation of cough.

4.2 Posology and method of administration

Posology

Adults:	5 to 10 ml every three to four hours.
Children 6 to 12 years:	2,5 to 5 ml every four hours.

The formulation is not suitable for children less than 6 years of age.

The safety in children under 6 years has not been established.

Method of administration

For oral use. Shake the bottle before use.

4.3 Contraindications

- Hypersensitivity to diphenhydramine hydrochloride, ammonium chloride and/or sodium citrate or to any of the excipients listed in section 6.1.
- Impaired hepatic or renal function.
- Patients with asthma and COPD (chronic obstructive pulmonary disease) (see section 4.4)
- Pregnancy and lactation (see section 4.6).
- Epilepsy. Antihistamines as contained in RELIEF-COFF EXPECTORANT may precipitate epileptiform seizures in patients with focal lesions of the cerebral cortex.

4.4 Special warnings and precautions for use

The use of RELIEF-COFF EXPECTORANT solution leads to drowsiness and impaired concentration, which is aggravated by the simultaneous intake of alcohol, and it is unsafe to drive a vehicle or be in charge of machinery while using RELIEF-COFF EXPECTORANT, as impaired decision making could lead to accidents.

RELIEF-COFF EXPECTORANT should be used cautiously in patients with cardiac failure,

hypertension, peripheral and pulmonary oedema. It should also be used with caution in patients with cardiovascular disease, glaucoma, prostatic hypertrophy, and patients with urinary retention.

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

Extreme caution should be exercised with patients taking RELIEF-COFF EXPECTORANT in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillizers, anticholinergic agents and tricyclic antidepressants, as their effects may be enhanced by diphenhydramine as contained in RELIEF-COFF EXPECTORANT (see section 4.5).

Monoamine-oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine hydrochloride as contained in RELIEF-COFF EXPECTORANT.

The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine hydrochloride as contained in RELIEF-COFF EXPECTORANT (see section 4.5).

Large doses of ammonium chloride as contained in RELIEF-COFF EXPECTORANT may cause nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, mental confusion, hyperchloraemic acidosis and hypokalaemia.

Excipients with known effect

RELIEF-COFF EXPECTORANT contains sodium methyl paraben. It may cause allergic reactions (possibly delayed).

RELIEF-COFF EXPECTORANT contains 7,69 mg sodium per 5 ml. This is less than 1 mmol sodium (23 mg) per 5 ml and is to say essentially 'sodium-free'.

RELIEF-COFF EXPECTORANT medicine contains 20 mg propylene glycol in each 5 ml.

4.5 Interactions with other medicines and other forms of interaction

Diphenhydramine hydrochloride as contained in RELIEF-COFF EXPECTORANT:

- The positive results of allergen skin tests may be suppressed.
- The anticholinergic effects of atropine and tricyclic antidepressants may be enhanced.
- Monoamine oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine.
- The warning symptoms of damage caused by ototoxic medicines such as aminoglycoside antibiotics, may be masked.
- The metabolism of other medicines in the liver, may be affected.
- The sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers, may be enhanced.

4.6 Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation have not been established (see section 4.3).

4.7 Effects on ability to drive and use machines

It is not always possible to predict to what extent RELIEF-COFF EXPECTORANT may interfere with the daily activities of a patient. RELIEF-COFF EXPECTORANT can cause drowsiness and less frequently dizziness, muscular weakness and incoordination, convulsions or seizures, confusion and blurred vision (see section 4.8). Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RELIEF-COFF EXPECTORANT

affects them.

4.8 Undesirable effects

Tabulated summary of adverse reactions

Diphenhydramine hydrochloride

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Less frequent	Haemolytic anaemia, leukopenia
Immune system disorders	Less frequent	Hypersensitivity reactions
Psychiatric disorders	Less frequent	Irritability, hallucination, nervousness, confusion
Nervous system disorders	Frequent	Drowsiness, dizziness, headache, paradoxical stimulation, psychomotor impairment
	Less frequent	Convulsions or seizures, tingling, nightmares
	Frequency unknown	Inability to concentrate, depression, euphoria, insomnia, tremors, muscle twitching
Eye disorders	Less frequent	Blurred vision
Ear and labyrinth disorders	Less frequent	Tinnitus
Cardiac disorders	Less frequent	Palpitations, dysrhythmias, tachycardia, hypotension
Respiratory, thoracic and mediastinal disorders	Frequent	Thickened respiratory tract secretions

System Organ Class	Frequency	Adverse reactions
	Less frequent	Chest discomfort, nasal dryness
Gastrointestinal disorders	Frequent	Dry mouth, stomach pain, nausea
	Less frequent	Epigastric pain, diarrhoea, anorexia, constipation, vomiting
Hepatobiliary disorders	Less frequent	Liver dysfunction
Skin and subcutaneous tissue disorders	Less frequent	Pruritus, rash, urticaria, photosensitivity
Renal and urinary disorders	Less frequent	Difficulty in micturition, urinary retention
General disorders and administration site conditions	Frequent	Asthenia

Ammonium chloride

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Frequent	Hyperchloraemic acidosis, hypokalaemia
Nervous system disorders	Frequency unknown	Progressive drowsiness, thirst, headache, hyperventilation, mental confusion
Gastrointestinal disorders	Frequency unknown	Nausea, vomiting

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the-Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
In addition, side effects can also be reported to info@pharmacorp.co.za.

4.9 Overdose

Symptoms

Retention of sodium leads to the accumulation of fluid, with cerebral oedema and peripheral and pulmonary oedema.
Symptoms of hypernatraemia may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypertension or hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Other symptoms of overdosage are gastrointestinal upset, drowsiness, hyperchloraemic acidosis and hypokalaemia.

Diphenhydramine hydrochloride

Overdosage may be fatal, especially in children in whom main symptoms are central nervous system stimulation and antimuscarinic effects, including ataxia, excitement, hypotension, drowsiness, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia, respiratory collapse, death may occur from respiratory failure. Deepening coma, cardiorespiratory collapse, and death may occur within 18 hours. In adults, the usual symptoms are of CNS depression with drowsiness, coma, and convulsions. Hypotension may also occur.

Ammonium chloride

Overdosage may cause nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, mental confusion, hyperchloraemic acidosis and hypokalaemia.

Treatment

Treatment is symptomatic and supportive and may include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 10.1 Antitussives and expectorants.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel colour (E150)

Hypromellose (E464)

Menthol

Propylene glycol (E1520)

Raspberry flavour

Saccharin sodium (E954)

Sodium methyl paraben (E219)

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in a cool, dry place in well closed containers.

Protect from light.

6.5 Nature and contents of container

100 ml or 200 ml HDPE bottles with white LDPE snap on caps or 100 ml or 200 ml round, amber plastic (PET – Polyethylene Terephthalate) bottles with a white polypropylene (PP) screw cap with liner.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

8. REGISTRATION NUMBER

27/10.1/0140

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 May 1994

10. DATE OF REVISION OF THE TEXT

17 February 2025.