Professional Prescribing Information

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

CLEAR COUGH®SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CLEAR COUGH® SYRUP

Each 5 ml of syrup contains:

Diphenhydramine Hydrochloride	14, 1 mg
Ammonium Chloride	135, 0 mg
Sodium Citrate	55, 0 mg
Preservative:	
Nipastat	0, 02 % *m/v*.
Alcohol	0,1 % *v/v*

Contains sugar:

Sucrose 1,5 g / 5ml

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution

A brown syrupy liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

- The alleviation of cough.

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4.2 Posology and Method of Administration

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

ADULTS: One to two medicine measures (5 – 10 ml) every three to four hours.

CHILDREN: 6 to 12 years: Half to one medicine measure (2, 5 - 5 ml) every four hours.

CLEAR COUGH® SYRUP should not be given to children under 6 years (see **section 4.3**).

Method of Administration

Doses must be taken orally with an adequate amount of fluid (half to one glass)

4.3 Contraindications:

- Hypersensitivity to diphenhydramine hydrochloride, ammonium chloride ,sodium citrate or any of the excipients listed in section 6.1
- **CLEAR COUGH®SYRUP** is contra-indicated in the presence of impaired hepatic or renal function.
- During an attack of asthma.
- Porphyria
- Concurrent use of **CLEAR COUGH® SYRUP** in patients taking monoamine oxidase inhibitors (MAOIs) is contra-indicated (see section 4.4).

- **CLEAR COUGH® SYRUP** is contraindicated in children under 6 years

4.4 Special warnings and precautions for use

The use of high doses of diphenhydramine-containing medicines, such as **CLEAR COUGH®SYRUP**, may lead to serious heart problems, seizures, coma and death.

Healthcare professionals are advised to:

• Be aware that **CLEAR COUGH® SYRUP** may be misused in order to cause a hallucinatory effect, and to alert caregivers about the risks related to its misuse in teenagers.

• Encourage teenagers and caregivers to read the **CLEAR COUGH® SYRUP** patient information leaflet included in the medicine package in order to familiarise themselves with the recommended dose and important safety information.

Advise consumers, parents and caregivers to store **CLEAR COUGH® SYRUP** and all other over-the-counter (OTC) and prescription medicines out of children's reach and sight. It is recommended that medicines should be locked up to prevent accidental poisonings by children and misuse by teenagers.

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 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.

CLEAR COUGH® SYRUP should not be taken concurrently with patients taking monoamine-oxidase inhibitors (MAOIs) or within 14 days of stopping therapy with MAOIs, as drowsiness and anticholinergic effects may be potentiated (see **section 4.5)**.

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tend to recur or is accompanied by high fever, rash or persistent headache, the patient should be advised to consult a doctor.

CLEAR COUGH® SYRUP should not be taken for persistent or chronic cough such as occurring with smoking, asthma, emphysema or where cough is accompanied by excessive phlegm (mucous).

Preparations containing sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy

CLEAR COUGH® SYRUP should be used cautiously in patients with cardiac failure, hypertension, peripheral and pulmonary oedema, cardiovascular disease, glaucoma, prostatic hypertrophy and patients with urinary retention. **CLEAR COUGH® SYRUP** should not be used in patients with impaired renal or liver function, or in pregnancy (see section 4.3)
The positive results of skin allergy tests may be suppressed.

Elderly population

Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects.
The elderly are particularly prone to dizziness, sedation, confusion, hypotension and anticholinergic effects.

Paediatric population

May cause excitability especially in children.

Sucrose:

CLEAR COUGH® SYRUP contains sucrose.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose –isomaltase insufficiency should not take/be given **CLEAR COUGH® SYRUP**

4.5 Interaction with other medicines and other forms of Interaction

The use of **CLEAR COUGH® SYRUP** in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives, tranquillisers, anticholinergic

medicines and tricyclic antidepressants is not recommended as their effects may be enhanced by diphenhydramine as contained in **CLEAR COUGH® SYRUP**.

Monoamine-oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effects of diphenhydramine, therefore, **CLEAR COUGH® SYRUP** should not be taken concurrently with patients taking MAOIs or within 14 days of stopping therapy with MAOIs.

The effects of medicines with anticholinergic activity such as tricyclic antidepressants or maprotiline will be potentiated. The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine, as in **CLEAR COUGH® SYRUP**.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Lactation

Safety in lactation has not been established.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

4.8 Undesirable effects

a) Summary of the safety profile

The most commonly reported adverse reactions caused by diphenhydramine is sedation which includes drowsiness, inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and incoordination

b) Tabulated list of adverse reactions

System Organ Class	**Frequency**	**Adverse reaction**

Blood and lymphatic system disorders	Less Frequent	Haemolytic anaemia, leukopenia, thrombocytopenia
Immune system disorder	Less Frequent	Hypersensitivity (allergic) reactions
Metabolism and nutrition disorders	Less Frequent	Anorexia, hyper-chloraemic acidosis and hypokalaemia
Psychiatric disorders	Frequent	Elation or depression, irritability, nightmares, euphoria, extra-pyramidal effects, mental confusion
Nervous system disorders	Frequent	Headache, drowsiness or progressive drowsiness, inability to concentrate, lassitude, dizziness, insomnia, nervousness, tremors, tingling, epileptiform seizures and convulsions
Eye disorders	Less Frequent	Blurred vision
Ear and labyrinth disorders	Less Frequent	Tinnitus
Cardiac disorders	Less Frequent	Hypotension, tachycardia, hyperventilation
Gastrointestinal disorders	*Frequent*	Gastro-intestinal disturbances, constipation, diarrhoea, epigastric pain, nausea, vomiting, dryness of mouth and thirst

Skin and subcutaneous tissue disorders	Less Frequent	Photosensitisation of the skin

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 **"6.04 Adverse Drug Reaction"** Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/

4.9 Overdose

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, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Other symptoms of overdosage are gastro-intestinal upset, drowsiness, hypochloraemic 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.

Ataxia, drowsiness, hyperpyrexia and hypotension may occur

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: A 10.1 Antitussives and expectorants

CLEAR COUGH® SYRUP prevents/reduces coughing and medicines that promote coughing and expulsion of mucous.

CLEAR COUGH® SYRUP has been formulated to alleviate cough.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other ingredients are:

- Alcohol
- Chloroform Spirits
- Clarks Caramel
- Menthol
- Nipastat
- Purified water
- Sodium Carboxymethyl Cellulose
- Sucrose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store in a cool place at or below 25 ^{0}C.

Protect from light

6.5 Nature and contents of container

100 ml, 200 ml, 2,5 litres and 25 litres containers

6.6 Special precautions for disposal and other handling

Return all unused or expired medicine to your pharmacist for safe disposal. Do not dispose of unused medicines in drains or sewage systems(e.g. toilets)

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext. 1

Roodepoort

1724

South Africa

8. REGISTRATION NUMBER(S)

W/10.1/367(SA)

S2 BOT 0500758 (Botswana) (100 ml)
NS1 90/10.1./00372 (Namibia) (100 ml, 200 ml, 2.5 litres)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 February 1990

10.DATE OF REVISON OF THE TEXT

22 November 2022