1.3.3.1 Professional Information (PI)

SCHEDULING STATUS: S2

1 NAME OF THE MEDICINE

DIPHAL EXPECTORANT (Solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Diphenhydramine Hydrochloride	14 mg
Ammonium Chloride	136 mg
Preservative: Nipastat	0,02 % *m/v*

Contains sugar (sucrose) 1 300 mg per 5 ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solutions.

A clear brown syrupy liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DIPHAL EXPECTORANT is indicated for the alleviation of cough in adults and children 6 years and older.

4.2 Posology and method of administration

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

Shake the bottle before use.

Adults: one to two medicine measures (5 to 10 ml) every three to four hours.

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

Paediatric population: The safety in children under 6 years has not been established (see section 4.3).

4.3 Contraindications

- Hypersensitivity to diphenhydramine hydrochloride, ammonium chloride or any of the ingredients of **DIPHAL EXPECTORANT**.
- **DIPHAL EXPECTORANT** is contra-indicated in the presence of impaired hepatic or renal function, and in patients with asthma and COPD (see section 4.4).
- **DIPHAL EXPECTORANT** should not be used with monoamine oxidase inhibitors including linezolid or within 14 days of stopping monoamine oxidase inhibitor including linezolid treatment (see section 4.4 and section 4.5).
- **DIPHAL EXPECTORANT** should not be used in children under the age of 6 years.

4.4 Special warnings and precautions for use

The use of **DIPHAL EXPECTORANT** solution leads to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol.

DIPHAL EXPECTORANT should be used cautiously in:

- patients with cardiac failure, hypertension, peripheral and pulmonary oedema and toxaemia of pregnancy.

- 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.

The positive results of skin allergy tests may be suppressed.

Extreme caution should be exercised with patients taking **DIPHAL EXPECTORANT** in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics, narcotics analgesic sedatives and tranquillisers and anticholinergic medicines and tricyclic antidepressants as their effects may be enhanced by diphenhydramine.

Monoamine-oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine hydrochloride.

The warning signs of damage caused by ototoxic medicines such as aminoglycosides may be masked by diphenhydramine hydrochloride.

- **DIPHAL EXPECTORANT** should not be taken for a persistent cough that occurs with smoking, asthma or emphysema.

Children who take **DIPHAL EXPECTORANT** may experience paradoxical hyperexcitability, nervousness, irritability or insomnia.

DIPHAL EXPECTORANT contains sucrose. Patient with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take **DIPHAL EXPECTORANT**.

DIPHAL EXPECTORANT contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

- **DIPHAL EXPECTORANT** may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsycotics.
- **DIPHAL EXPECTORANT** should not be used simultaneously with monoamine oxidase inhibitors including linezolid (see section 4.3).
- Warning signs of damage caused by ototoxic medicines such as aminoglycoside antibiotics may be masked by **DIPHAL EXPECTORANT** (see section 4.4).
- **DIPHAL EXPECTORANT** may suppress the cutaneous histamine response to allergen extracts. The use of **DIPHAL EXPECTORANT** should be stopped at least 72 hours before testing begin.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

The use of **DIPHAL EXPECTORANT** solution leads to drowsiness and impaired concentration and it is unsafe to drive a vehicle or be in charge of machinery while using **DIPHAL EXPECTORANT**, as impaired decision making could lead to accidents.

4.8 Undesirable effects

Diphenhydramine hydrochloride:

Blood and lymphatic system disorders:

Less frequent: haemolytic anaemia, leucopenia.

Nervous system disorders:

Frequent: drowsiness, dryness of mouth.

Less frequent: dizziness, muscular weakness and incoordination, heaviness and weakness of the hands, headache, convulsions or seizures, tingling, confusion, nightmares, nervousness, restlessness or irritability.

Frequency unknown: inability to concentrate, lassitude, elation or 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, and hypotension.

Respiratory, thoracic and mediastinal disorders:

Less frequent: tightness in chest.

Gastrointestinal disorders:

Frequent: stomach pain, nausea.

Less frequent: epigastric pain, diarrhoea, anorexia, constipation, vomiting.

Skin and subcutaneous tissue disorders:

Less frequent: skin rash, photo-sensitisation of the skin, hypersensitivity reactions.

Renal and urinary disorders:

Less frequent: difficulty in micturition.

Ammonium chloride:

Blood and lymphatic system disorders:

Frequency unknown: hyperchloraemic acidosis, hypokalaemia.

Nervous system disorders:

Frequency unknown: progressive drowsiness, thirst, headache, hyperventilation, mental confusion.

Gastrointestinal disorders:

Frequency unknown: nausea, vomiting.

Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

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 gastrointestinal 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.
Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

Category A 10.1 Antitussives and expectorants.

Pharmacological action

Diphenhydramine hydrochloride is an antihistamine with cough suppressant properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel 4800 (flavour)

Essence of raspberry No. 1 (flavour)

Invert syrup

Menthol (flavour)

Nipastat

Propylene glycol

Purified water

Sodium citrate

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 °C. Protect from light.

6.5 Nature and contents of container

100 ml round amber PVC bottles with white LDPE screw on or snap-on caps, or

200 ml round amber PVC bottles with white LDPE snap-on caps.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare CC

374 Anderson Street

Menlo Park, Pretoria, 0081

RSA

8 REGISTRATION NUMBER

46/10.1/0087

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORIZATION

Date of registration: 25 March 2019

10 DATE OF REVISION OF THE TEXT

25 October 2022

DIP-2