SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

BETALIN® SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

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

Preservative: Nipastat 0,02 % *m/v*

Contains Sugar:

Sucrose 1,3g /5 ml

3. PHARMACEUTICAL FORM

Syrup

A brown syrupy liquid.

4.CLINICAL PARTICULARS

4.1 Therapeutic indications

The alleviation of cough.

4.2 Posology and method of administration

Should not be given to children under 6 years.

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

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

4.3 Contraindications

- Hypersensitivity (allergy) to any of the ingredients listed in section 6.1.
- **BETALIN®** is contra-indicated in the presence of impaired hepatic function (decrease in liver function) or impaired renal function (decrease in kidney function).
- During an attack of asthma.

  Safety in pregnancy and lactation has not been established.
- Porphyria.
- **BETALIN®** is contra-indicated under the age of 6 years.

4.4 Special warnings and precautions for use

- Use with caution in patients with heart disease. Doses must be taken with an adequate amount of fluid (half to one glass).
- 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, consult a doctor.
- Do not take this product for persistent or chronic cough such as occur with smoking, asthma, emphysema or where cough is accompanied by excessive phlegm (mucous) unless directed by a doctor.
- Caution should be used when the following medical conditions exist:

  Prostatic hypertrophy

  Narrow angle glaucoma

  Emphysema or chronic bronchitis
- The positive results of skin allergy (hypersensitivity) tests may be suppressed.
- **BETALIN®** should be used cautiously in patients with hypertension.

Paediatric population

- May cause excitability especially in children.
- Use is not recommended in newborn or premature infants.

- This age group has an increased susceptibility to anticholinergic side effects such as central nervous system excitation and an increased tendency towards convulsions.

Elderly population

- The elderly are particularly prone to dizziness, sedation, confusion, hypotension and anticholinergic effects.
- **BETALIN®** contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Extreme caution should be exercised by patients taking **BETALIN®** in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesics (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillisers (agent used for calming nerves) and anticholinergic agents (a substance to stop the release of certain nerve impulses involving acetylcholine) and tricyclic antidepressants as their effects may be enhanced by diphenhydramine.

Monoamine-oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effects of diphenhydramine, Concurrent use is not recommended. The effects of drugs with anticholinergic activity such as tricyclic antidepressents or maprotiline will be potentiated. The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established (see **section 4.3**).

Breastfeeding

Safety in lactation has not been established (see **section 4.3**).

4.7 Effects on ability to drive and use machines

The use of **BETALIN®** 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 this medicine, as impaired decision making could lead to an accident.

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
Musculoskeletal, and connective tissue disorders	Less Frequent	Muscular weakness and incoordination, muscle twitching, tightness of chest, heaviness and weakness of the hands
Renal and urinary disorders	Less frequent	Difficulty in micturition

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. Health care providers 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/8

4.9 Overdose

Retention of sodium leads to the accumulation of fluid, with cerebral oedema (accumulation of fluid on the brain), peripheral oedema (swelling of the hands and feet due to retained fluid) and pulmonary oedema (excessive fluid accumulation in the lungs).

Symptoms of hypernatraemia (too much sodium in the blood) may include restlessness, weakness, thirst, reduced salivation (secretion of saliva) and lachrymation (secretion of tears), swollen tongue, flushing of the skin, pyrexia (fever), dizziness, headache, oliguria (reduced urine production), hypotension (low blood pressure), tachycardia (increased rate of heart beat), delirium (rapid succession of confused and unconnected ideas often associated with illusions and hallucinations), hyperpnoea (abnormally rapid and deep breathing) and respiratory arrest (loss of effective ability to breathe). Other symptoms of overdosage are gastro-intestinal (affecting the stomach and intestines) upset, drowsiness, hyperchloraemic acidosis (abnormally high levels of chloride in the blood causing the blood to be acidic), and hypokalaemia (low blood levels of potassium).

Diphenhydramine hydrochloride overdosage may be fatal especially in children who's main symptoms are central nervous system (brain) stimulation and antimuscarinic (the opposite effect of acetylcholine) effects including ataxia (loss of muscle co-ordination), excitement, hallucinations (false perceptions), muscle tremor, convulsions (fits), dilated pupils, dry mouth, flushed face and hyperpyrexia (abnormally high body temperature), respiratory collapse (failure of the breathing process), death may occur from respiratory failure (inability to breathe).

Ataxia (loss of muscle co-ordination), drowsiness, hyperpyrexia (abnormally high body temperature), hypotension (low blood pressure) may occur.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A 10.1 Antitussives and expectorants

BETALIN® prevents/reduces coughing and medicines that promote coughing and expulsion of mucous.

BETALIN® has been formulated to alleviate cough.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Clarks caramel 48000
- essence of raspberry no. 1
- invert syrup
- menthol
- 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, 200 ml, 2,5 L and 25 L containers.

6.6 Special precautions for disposal and other handling

Return all unused or expired medicines 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)

L/10.1/415 (S.A.)

S3	BOT 0500773 (Botswana) (100 ml)
NS1	90/10.1/00366 (Namibia) (100 ml, 200 ml, 2,5 L, 25 L)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 JUNE 1980

10 DATE OF REVISON OF THE TEXT

30 September 2022