1.3.1.1 Current Approved Professional Information for Medicines for Human Use

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

BETAFED SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Triprolidine HCl	1,25 mg
Pseudoephedrine HCl	30,00 mg
Preservatives:	
Methyl hydroxybenzoate	0,18 % *m/v*
Propyl hydroxybenzoate	0,02 % *m/v*

Alcohol content 1,92 % *v/v*

Contains sugar:

Liquid glucose: 0,25 g /5 ml

Sorbitol 70 %: 2,5 ml / 5 ml

Glycerol: 0,25 ml / 5 ml

Contains sweetener: Saccharin sodium: 0,5 mg / 5 ml

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

A clear, bright yellow, slightly viscous, pleasant tasting syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BETAFED SYRUP is indicated for the relief of symptoms associated with colds and influenza such as nasal and sinus congestion, allergic rhinitis, vasomotor rhinitis and the common cold.

4.2 Posology and method of administration

Adults and children over 12 years: 2 medicine measures (10 ml)
orally three times daily.
Children 6 to 12 years: 1 medicine measure (5 ml) orally three times
daily.
Children 2 to 5 years: ½ medicine measure (2,5 ml) orally three times
daily.

Method of Administration

For oral use.

4.3 Contraindications

- Hypersensitivity to pseudoephedrine hydrochloride, triprolidine hydrochloride or to any of the excipients listed in section 6.1.
- **BETAFED SYRUP** is contraindicated in patients who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks as this may cause a rise in blood pressure. The antibacterial agent furazolidone is known to cause a dose-related inhibition

of monoamine oxidase. For this reason **BETAFED SYRUP** and furazolidone should not be taken together.

- **BETAFED SYRUP** is contraindicated during acute attacks of asthma.
- **BETAFED SYRUP** is contraindicated in children under the age of 2 years.
- **BETAFED SYRUP** is contraindicated in severe hypertension or uncontrolled hypertension
- **BETAFED SYRUP** is contraindicated in severe acute or chronic kidney disease/renal failure

4.4 Special warnings and precautions for use

The use of **BETAFED SYRUP** may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Great care is needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders, including arteriosclerosis, hypertension or aneurysms.

Care is required when pseudoephedrine is given to patients with hyperthyroidism, diabetes mellitus, closed-angle glaucoma or prostatic enlargement. Caution should be exercised in the presence of severe renal or hepatic impairment. Symptoms of central nervous system excitation, may occur, including sleep disturbances and hallucinations. Difficulty with micturition may also be experienced. Dyspnoea; altered metabolism including disturbances of glucose metabolism, sweating and hypersalivation are possible. Fixed drug eruption to pseudoephedrine, taking the form of erythematous nummular patches and lichenoid skin eruption due to triprolidine have been reported. Paradoxical central nervous system stimulation may occur particularly in children, with insomnia, nervousness, tachycardia, tremors and convulsions. Epileptiform seizures may be precipitated in patients with focal lesions of the cerebral cortex. Allergic reactions and cross-sensitivity to related medicines are possible with systemic triprolidine administration. Blood disorders including agranulocytosis, leukopenia and haemolytic anaemia have been reported. Elderly patients are more susceptible to the central

nervous system depressant and hypotensive effects of antihistamines even at therapeutic doses.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

BETAFED SYRUP contains:

Glucose: Patients with rare glucose-galactose malabsorption should not take this medicine.

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Sorbitol 70 % solution: Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Glycerol: Glycerol may cause headache, stomach upset and diarrhoea.

The excipients methyl hydroxybenzoate, propyl hydroxybenzoate and sunset yellow may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of **BETAFED SYRUP** with other sympathomimetic medicines, such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants, or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure largely because of interaction with pseudoephedrine. Pseudoephedrine may partially reverse the hypotensive action of medicines which interfere with sympathetic activity including bretylium, bethanidine, guanethidine, debrisoquine and methyldopa.

Pseudoephedrine should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation. An increased risk of arrhythmias may also occur if pseudoephedrine is given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants. Triprolidine may have an additive antimuscarinic action with other antimuscarinic medicines, such as atropine and the tricyclic antidepressants.

BETAFED SYRUP may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers. **BETAFED SYRUP** could mask the warning signs of damage caused by ototoxic medicines such as aminoglycoside antibiotics, due to its triprolidine content.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of **BETAFED SYRUP** in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Patients should be warned not to drive or operate dangerous machinery.

4.8 Undesirable effects

System Organ Class (SOC)	Frequent	Less frequent	Frequency unknown

Blood and Lymphatic System Disorders		Blood disorder	
Immune System Disorders		Hypersensitivity – cross sensitivity may occur with other sympathomimetics	
Psychiatric Disorders	Insomnia[1], nervousness[1]	Hallucination, confusional state, depression, sleep disorder	Agitation, anxiety, delusion, euphoric mood, hallucination, visual irritability, restlessness
Nervous System Disorders	Headache, dizziness[1], paradoxical drug reaction, psychomotor hyperactivity, somnolence	Extrapyramidal disorder, seizure, tremor	Cerebrovascular accident, epilepsy, paraesthesia, posterior reversible, encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS)
Eye Disorders	Vision blurred		Ischaemic optic neuropathy
Cardiac Disorders		Dysrhythmia, palpitations	Myocardial infarction / Myocardial ischaemia, tachycardia
Vascular Disorders		Hypotension	Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Increased viscosity of bronchial secretion		Dry throat, epistaxis, nasal dryness
Gastrointestinal Disorders	Dry mouth, gastrointestinal disorder, nausea[1]		Abdominal discomfort, ischaemic colitis, vomiting
Hepatobiliary Disorders		Liver disorder	

Skin and Subcutaneous Tissue Disorders			Angioedema, pruritus, rash, severe skin reactions, including acute generalised exanthematous pustulosis (AGEP), urticaria
Renal and Urinary Disorders	Urinary retention		Dysuria
General Disorders and Administration Site Conditions			Fatigue, hyperpyrexia

[1]Adverse events reported by ≥ 1 % of subjects in randomised, placebo-controlled trials with single-ingredients pseudoephedrine

No differences between adult and paediatric safety profiles have been identified.

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 provders 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

Overdosage due to triprolidine may be fatal, especially in children in whom the main symptoms are central nervous system stimulation and antimuscarinic effects: ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults, the usual symptoms of overdosage are drowsiness, coma and convulsions. Weakness, dizziness, incoordination, difficulty with micturition, respiratory depression,

hypotension, agitation, irritability, hypertension, palpitations, restlessness and tachycardia, may occur. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A.5.8 Preparations for the common cold including nasal decongestants and antihistaminics.

Pharmacotherapeutic group: Sympathomimetics, pseudoephedrine, combinations. ATC code: R01BA52

BETAFED SYRUP has antihistaminic and decongestant properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Alcohol 96 %
- Flavour honey 73425-H
- Glycerol
- Liquid Glucose
- Quinolene yellow H8573 (C.I. 47005)
- Methyl Hydroxybenzoate
- Propyl Hydroxybenzoate
- Purified water
- Saccharin sodium
- Sodium chloride
- Sodium cyclamate
- Sorbitol solution 70 %
- Sucrose
- Sunset yellow H8070 (C.I.15985)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in well-closed containers at or below 25 ˚C.

Protect from light.

6.5 Nature and contents of container

100 ml in amber glass bottles.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBER(S)

31/5.8/0249 (S.A)

NS1	14/5.8/0635 (Namibia)

NS3	BOT 0500762 (Botswana)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 June 1998

10. DATE OF REVISON OF THE TEXT

24 March 2024