

## Professional Information

### SCHEDULING STATUS

S2

#### 1. NAME OF THE MEDICINE

BETAFED SYRUP

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Tripolidine HCl	1,25 mg
Pseudoephedrine HCl	30,00 mg
Preservatives:	
Methyl hydroxybenzoate	0,18 % <i>m/v</i>
Propyl hydroxybenzoate	0,02 % <i>m/v</i>

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

<b>Blood and Lymphatic System Disorders</b>		Blood disorder	
<b>Immune System Disorders</b>		Hypersensitivity – cross sensitivity may occur with other sympathomimetics	
<b>Psychiatric Disorders</b>	Insomnia <sup>1</sup> , nervousness <sup>1</sup>	Hallucination, confusional state, depression, sleep disorder	Agitation, anxiety, delusion, euphoric mood, hallucination, visual irritability, restlessness
<b>Nervous System Disorders</b>	Headache, dizziness <sup>1</sup> , paradoxical drug reaction, psychomotor hyperactivity, somnolence	Extrapyramidal disorder, seizure, tremor	Cerebrovascular accident, epilepsy, paraesthesia, posterior reversible, encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS)
<b>Eye Disorders</b>	Vision blurred		Ischaemic optic neuropathy

<b>Cardiac Disorders</b>		Dysrhythmia, palpitations	Myocardal infarction / Myocardial ischaemia, tachycardia
<b>Vascular Disorders</b>		Hypotension	Hypertension
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	Increased viscosity of bronchial secretion		Dry throat, epistaxis, nasal dryness
<b>Gastrointestinal Disorders</b>	Dry mouth, gastrointestinal disorder, nausea <sup>1</sup>		Abdominal discomfort, ischaemic colitis, vomiting
<b>Hepatobiliary Disorders</b>		Liver disorder	
<b>Skin and Subcutaneous Tissue Disorders</b>			Angioedema, pruritus, rash, severe skin reactions, including acute generalised exanthematous pustulosis (AGEP), urticaria
<b>Renal and Urinary Disorders</b>	Urinary retention		Dysuria
<b>General Disorders and</b>			Fatigue, hyperpyrexia

<b>Administration</b>			
<b>Site Conditions</b>			

<sup>1</sup>Adverse events reported by  $\geq 1$  % 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 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**

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
- Quinoline 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**

24 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)
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NS3	BOT 0500762 (Botswana)
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**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

01 June 1998

**10. DATE OF REVISION OF THE TEXT**

24 March 2024