1.3.2 Current Approved Patient Information Leaflet

SCHEDULING STATUS S2

BETAFED SYRUP

Pseudoephedrine hydrochloride, Triprolidine hydrochloride

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

Read all of this leaflet carefully because it contains important information for you

BETAFED SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BETAFED SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BETAFED SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What BETAFED SYRUP is and what it is used for

2. What you need to know before you take BETAFED SYRUP
3. How to take BETAFED SYRUP
4. Possible side effects
5. How to store BETAFED SYRUP
6. Contents of the pack and other information

1. What BETAFED SYRUP is and what it is used for

BETAFED SYRUP is a medicine which is used to relieve the symptoms of colds and allergies including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses. The liquid contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes.

2. What you need to know before you take BETAFED SYRUP

Do not take BETAFED SYRUP :

- if you are hypersensitive (allergic) to triprolidine, pseudoephedrine or any of the other ingredients of BETAFED SYRUP (listed in section 6)
- if you are taking, or have taken in the last two weeks, drugs for **depression** known as Monoamine Oxidase Inhibitors (MAOIs), as this may cause a rise in blood pressure.
- if you or your child have asthma i.e. breathing problems
- if your child is under the age of 2 years.

Warnings and precautions

Take special care with BETAFED SYRUP :

- if you have high blood pressure or heart disease such as dysrhythmia (changes in heart rate), tachycardia (fast heart beat), atherosclerosis (disease of the arteries in which blood vessel walls thicken), or aneurysm (swelling and weakening of part of a blood vessel)

- if you have an overactive thyroid
- if you have diabetes (high level of blood sugar)
- if you have glaucoma (increased pressure in the eye)
- if you have prostate problems (difficulty with passing water or needing to pass water often)
- if you have liver or kidney problems
- if you are elderly

Other medicines and BETAFED SYRUP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion and asthma)
- tricyclic antidepressants (medicine used to treat mood disorders)
- monoamine oxidase inhibitors (medicine for treatment of depression)
- antihypertensives (drugs used to treat high blood pressure) such as bretylium, betanidine, debrisoquine, *guanethidine* and methyldopa)
- cyclopropane, halothane or other anaesthetics agents (medicine used to prevent pain and discomfort during surgery)
- cardiac glycoside, quinidine (medicine used to treat heart failure and certain irregular heartbeats)
- atropine (medicine that increases heart rate and reduces saliva and other secretions)

- alcohol, sedatives (drugs used to treat anxiety and tension), hypnotics (sleeping tablets including barbiturates) and tranquilisers (medicine used to treat anxiety and tension)
- narcotic analgesics (pain killers or pain relieving medicine)
- aminoglycoside antibiotics (medicines for treatment of bacterial infection such as gentamicin).

BETAFED SYRUP with food and drink

Do not drink alcohol together with BETAFED SYRUP.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take **BETAFED SYRUP** if you are pregnant or breastfeeding your baby as safety has not been established.

Driving and using machines

BETAFED SYRUP may make you feel drowsy.

If affected, do not drive because BETAFED SYRUP will interfere with your ability to drive or operate any tools or machines.

BETAFED SYRUP contains sucrose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

BETAFED SYRUP contains sorbitol 70 % solution

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

BETAFED SYRUP contains glycerol

May cause headache, stomach upset and diarrhoea.

BETAFED SYRUP contains 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'.

3. How to take BETAFED SYRUP

Do not share medicines prescribed for you with any other person.

Always take BETAFED SYRUP exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:
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.

If you have the impression that the effect of BETAFED SYRUP is too strong or too weak, tell your doctor or pharmacist.

If you take more BETAFED SYRUP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BETAFED SYRUP

If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

Do not take a double dose to make up for a single missed dose.

4. Possible side effects

BETAFED SYRUP can have side effects.

Not all side effects reported for BETAFED SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BETAFED SYRUP, please consult your health care provider for advice.

If any of the following happens, stop taking BETAFED SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized

  Exanthematous Pustulosis - AGEP) may occur.
- sudden stomach pains, passing blood in your stools or bleeding from your back passage and diarrhoea.
- severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- allergic reaction including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.

- hallucinations, paranoid delusions or fits.

These are a very serious side effects. If you have them, you may have had a serious allergic reaction to **BETAFED SYRUP.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- restlessness or sleep disturbances
- a fast or irregular heartbeat or an increased awareness of your heartbeat (palpitations).
- trouble passing water (especially men with prostate problems).
- reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- difficulty sleeping, nervousness, dizziness or feeling jittery
- drowsiness
- blurred vision
- thickened mucus, dry mouth, nausea or an upset stomach.

Less frequent side effects:

- confusion or depression
- tremor, shakiness or slurred speech
- low blood pressure.

Frequency unknown:

- stroke

- heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina)
- agitation, anxiety, irritability or feelings of extreme happiness
- tingling or numbness of the hands or feet (pins and needles)
- high blood pressure
- inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- vomiting or stomach discomfort
- pain when passing urine
- feeling tired
- very high fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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

By reporting side effects, you can help provide more information on the safety of BETAFED SYRUP.

5. How to store BETAFED SYRUP

- Store all medicines out of reach of children.
- Store in well-closed containers at or below 25 ˚C.
- Protect from light.
- Do not refrigerate
- Store in the original package / container

- Keep the container in the outer carton
- Keep the container tightly closed
- Do not use after the expiry date stated in the packaging material
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What BETAFED SYRUP contains

The active substance is pseudoephedrine hydrochloride and triprolidine hydrochloride.

The other ingredients are 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).

What BETAFED SYRUP looks like and contents of the pack

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

100 ml in amber glass bottles.

Holder of Certificate of Registration

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