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| **Applicant/PHCR:** | Ranbaxy Pharmaceuticals (Pty) Ltd |
| **Product proprietary name:** | BETALIX DECONGESTANT |
| **Dosage form and strength:** | Elixir; Each 5 ml contains chlorpheniramine maleate 2 mg, phenylephrine hydrochloride 2,5 mg, phenylpropanolamine hydrochloride 2,5 mg |
| **Date of amendment:** | July 2021 |

**1.5.5 Proposed Patient Information Leaflet**

**SCHEDULING STATUS**

S2

**BETALIX DECONGESTANT elixir**

Chlorpheniramine maleate, Phenylpropanolamine hydrochloride, Phenylephrine hydrochloride

Contains sugar: Sorbitol solution 70 % 3,5 ml per 5 ml

Contains no alcohol

**Read all of this leaflet carefully because it contains important information for you/your child**

- BETALIX DECONGESTANT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BETALIX DECONGESTANT carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share BETALIX DECONGESTANT with any other person.
- Ask your healthcare 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 the leaflet**


1. What BETALIX DECONGESTANT is and what it is used for
2. What you need to know before you take/give BETALIX DECONGESTANT
3. How to take/give BETALIX DECONGESTANT
4. Possible side effects
5. How to store BETALIX DECONGESTANT

6. Contents of the pack and other information

## 1. What BETALIX DECONGESTANT is and what it is used for

BETALIX DECONGESTANT contains chlorpheniramine maleate, phenylpropanolamine hydrochloride and phenylephrine hydrochloride. Chlorpheniramine maleate belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergic reactions. Phenylpropanolamine hydrochloride and phenylephrine hydrochloride are decongestants which unblock your nose and sinuses helping you breathe more easily.

BETALIX DECONGESTANT is used for:

- the relief of a blocked nose associated with colds and flu, allergies or inflammation of the sinuses.
- the relief of congestion in the Eustachian tube (tube that runs from the middle ear to the nasal passages and throat) as an adjunct to treatment of an infection in the middle ear.

## 2. What you need to know before you take/give BETALIX DECONGESTANT

**Do not take/give BETALIX DECONGESTANT**

- if you/your child are allergic to chlorpheniramine maleate, phenylpropanolamine hydrochloride or phenylephrine hydrochloride, or any of the other ingredients of BETALIX DECONGESTANT (listed in section 6).
- if you/your child have heart or thyroid problems.
- during an asthma attack.
- if you are taking a medicine of the class known as monoamine oxidase inhibitors (MAOIs, e.g. selegiline, moclobemide), which are used as antidepressants, or if you had taken any medicine of this group in the past 14 days.
- if you/your child has diabetes.

- if you are pregnant or breastfeeding your baby.
- in children under the age of two years.

**Warnings and precautions**

Take special care with BETALIX DECONGESTANT:

- as after 5-7 days tolerance may occur and BETALIX DECONGESTANT loses effect. BETALIX DECONGESTANT should not be taken/given for more than 7 days. If symptoms do not improve, or are accompanied by fever, consult a doctor.
- as exceeding the recommended dosage may result in nervousness, dizziness, sleeplessness; tremors or changes in the way your heart beats, severely high blood pressure and bleeding in the brain.
- if you have high blood pressure, pressure in the eyes or an enlarged prostrate.
- if you have kidney problems.

**Other medicines and BETALIX DECONGESTANT**

Always tell your healthcare provider if you/your child are taking any other medicine (this includes all complementary or traditional medicines).

- Medicines to treat or prevent clinical depression (e.g. monoamine oxidase inhibitors, tricyclic antidepressants).
- Any of the group of medicines called antimuscarinics (e.g. atropine).
- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers).
- Aminoglycoside antibiotics used to treat bacterial infections.
- Phenytoin used to treat epilepsy.
- Anaesthetics (e.g. cylcopropane, halothane).

- Medicines used to treat heart conditions (e.g. cardiac glycosides, quinidine).
- Medicines used to treat high blood pressure.

**BETALIX DECONGESTANT with food and drink**

BETALIX DECONGESTANT should not be taken with alcohol.

**Pregnancy, breastfeeding 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 healthcare provider for advice before taking BETALIX DECONGESTANT.

**Driving and using machines**

BETALIX DECONGESTANT may cause drowsiness and impair your concentration. If you experience these side effects, do not drive or operate machinery.

**BETALIX DECONGESTANT contains sorbitol**

BETALIX DECONGESTANT contains sorbitol and may cause gastrointestinal discomfort and have a mild laxative effect. Sorbitol is a source of fructose. If your doctor has told you that you/your child have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you/your child take or receive BETALIX DECONGESTANT.

## 3. HOW TO TAKE/GIVE BETALIX DECONGESTANT

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

Always take/give BETALIX DECONGESTANT 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:

Children 6 – 12 years: One 5 ml medicine measureful 3 or 4 times daily.

Children 2 – 6 years: Half a 5 ml medicine measureful 3 or 4 times daily.

**If you take/give more BETALIX DECONGESTANT 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/give BETALIX DECONGESTANT**

If you forget to take/give a dose, take/give it as soon as you remember. Do not take/give a double dose to make up for a forgotten dose.

**4. Possible side effects**

BETALIX DECONGESTANT can have side effects.

Not all side effects reported for BETALIX DECONGESTANT are included in this leaflet. Should your/your child's general health worsen or if you/your child experience any untoward effects while taking BETALIX DECONGESTANT, please consult your healthcare provider for advice.

**If any of the following happens, stop taking/giving BETALIX DECONGESTANT and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching, peeling of the skin.

These are all very serious side effects. If you/your child have them, you/your child may have had a serious reaction to BETALIX DECONGESTANT. You/your child 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:**

- bleeding or increased tendency to bleed, persistent sore throat and frequent infections, fever, and/or anaemia,
- nervousness, irritability, restlessness, and excitability (especially in children), depression, a feeling of intense excitement and happiness, fear, anxiety, confusion, seeing, hearing, or believing things that are not real, seizures,
- severe eye pain, a red eye and reduced or blurred vision, dilation of the pupil of the eye,
- changes in the way your heart beats, chest pain,
- bleeding in the brain with symptoms such as a sudden, severe headache, include numbness or weakness in part of the face, difficulty speaking or difficulty walking,
- yellowing of skin and whites of eyes (jaundice), dark urine, and tiredness which may be symptoms of liver problems,
- difficulty in urination, less urine than is normal for you, no urination.

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

**Tell your doctor if you notice any of the following:**

Frequent side effects:

- sedation varying from slight drowsiness to deep sleep, difficulty in falling/staying asleep, lack of energy, dizziness, headache,
- increase in blood pressure,
- nausea, vomiting, diarrhoea,

Less frequent side effects:

- nightmares, incoordination, impaired concentration,
- ringing in the ears,
- low blood pressure,
- thickening of phlegm,
- constipation, increased appetite, stomach pain, heartburn, dry mouth,
- sensitivity to light,
- muscular weakness, twitching, tightness of the chest,

Side effects with unknown frequency:

- tremor,
- reddening of the skin, sweating,
- reduced appetite, increase in saliva production.

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

**Reporting of side effects**

If you/your child gets side effects, talk to your doctor or pharmacist. 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 BETALIX DECONGESTANT.

## 5. How to store BETALIX DECONGESTANT

- Store all medicines out of reach of children.
- Store at or below 25 °C and protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label or bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What BETALIX DECONGESTANT contains

The active substances are 2 mg chlorpheniramine maleate, 2,5 mg phenylpropanolamine hydrochloride and 2,5 mg phenylephrine hydrochloride.

Preserved with sodium benzoate 0,2 % *m/v*

The other ingredients are:

Brilliant blue (CI 42090), citric acid anhydrous, sodium benzoate, sorbitol solution 70 %, sunset yellow (CI 15985), purified water, quinolene yellow (CI 47005), trusil cream soda, xanthan gum

### What BETALIX DECONGESTANT looks like and contents of the pack

A sweet, light green, cream-soda flavoured elixir.

Amber glass or HDPE bottles containing 100 ml and 200 ml. Sealed with a white tamper-evident closure.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill Ext. 1

Roodepoort 1724

South Africa

**This leaflet was last revised in**

Will be allocated by SAHPRA upon approval of update

**Registration numbers**

28/5.8/0648

Namibia: NS1 04/5.8/0994

**Access to the corresponding Professional Information**

To follow