

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

**MONTELUKAST CHEW BIOTECH 4 Chewable Tablets**

**MONTELUKAST CHEW BIOTECH 5 Chewable Tablets**

**MONTELUKAST BIOTECH 10 Film-coated tablets**

**Montelukast**

**Each MONTELUKAST CHEW BIOTECH 4 contains:**

**Sweetener: Aspartame 2,40 mg**

**Sugar: Mannitol 179,76 mg**

**Each MONTELUKAST CHEW BIOTECH 5 contains:**

**Sweetener: Aspartame 3,00 mg**

**Sugar: Mannitol 224,71 mg**

**Each MONTELUKAST BIOTECH 10 contains:**

**Sugar: lactose monohydrate 85,81 mg**

**Lecithin (soya) contained in film-coating.**

**Please read this leaflet carefully before you start taking MONTELUKAST BIOTECH tablets.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MONTELUKAST BIOTECH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

1. What MONTELUKAST BIOTECH is and what it is used for
2. What you need to know before you take MONTELUKAST BIOTECH

Montelukast Biotech 4, 5, 10 mg tablets range (45/10.2.2/0475/6/7)  
*Contains montelukast sodium equivalent to 4 mg, 5 mg, 10 mg  
montelukast, respectively.*

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3. How to take MONTELUKAST BIOTECH
4. Possible side effects
5. How to store MONTELUKAST BIOTECH
6. Contents of the pack and other information

### **1. What MONTELUKAST BIOTECH is and what it is used for**

MONTELUKAST BIOTECH is used for the treatment of asthma, including preventing your asthma symptoms.

In adult asthmatic patients in whom MONTELUKAST BIOTECH is used for asthma, it may also provide some relief of the symptoms of seasonal allergies.

### **2. What you need to know before you take MONTELUKAST BIOTECH**

#### **Do not take MONTELUKAST BIOTECH tablets:**

- If you are allergic to montelukast or any of the other ingredients of MONTELUKAST BIOTECH (listed in section 6).
- If you are pregnant or breastfeeding.

#### **Do not give your child MONTELUKAST BIOTECH to take:**

- If he / she is allergic to montelukast or any of the other inactive ingredients included in the tablets.
- If he / she is under the age of 2 years as the safety and efficacy of the 4 mg tablets have not been demonstrated.
- If he / she is under the age of 6 years as the safety and efficacy of 5 mg tablets have not yet been demonstrated.
- If he / she is under the age of 15 years as the safety and efficacy of 10 mg tablets have not been demonstrated.
- MONTELUKAST BIOTECH 10 contains soya oil. If you are allergic to peanut or soya, do not use MONTELUKAST BIOTECH 10.

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## Warnings and precautions

Take special care with MONTELUKAST BIOTECH:

- MONTELUKAST BIOTECH should not be used for the treatment of an acute asthma attack as the effectiveness has not been demonstrated. You should or your child however continue to use it during worsening of asthma symptoms. You should have appropriate inhalation medication available to treat worsening of asthma.
- MONTELUKAST BIOTECH can unmask a vascular disorder named Churg-Strauss. If you or your child experience any of the following seek medical advice immediately: any type of rash, worsening of asthma symptoms, increased heartbeat, chest pain, together with headache, fever, muscle pains and weight loss.
- MONTELUKAST BIOTECH can cause certain neuropsychiatric events. If you or your child experience any of the following seek medical advice: aggression, anxiousness, abnormal dreams or hallucinations, depression, difficulty sleeping (insomnia), irritability, restlessness, suicidal thoughts and behaviour. See “Possible Side Effects”.
- MONTELUKAST BIOTECH should be used every day even when you or your child experiences no asthma symptoms.
- You should contact your doctor if your asthma is not well controlled.
- You should use MONTELUKAST BIOTECH together with other medication your doctor might have prescribed for you or your child to use before exercise.
- You should always have the inhaled rescue medication for acute asthma attacks with you and available to use in an emergency situation.
- If you or your child’s asthma symptoms get worse, or if you must increase the use of you or your child’s inhaled rescue medicine for asthma attacks in a 24-hour period, you should contact your doctor immediately.
- If aspirin normally makes your asthma worse, do not take aspirin or other non-steroidal anti-

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inflammatory drugs (NSAIDs) such as ibuprofen.

- If you or your child have liver problems, tell your doctor.
- If your asthma worsens during exercise, you should use your usual inhalation medication as prescribed for prevention of an asthma attack.
- You should not decrease the dose or stop any medication prescribed for the treatment of asthma, unless instructed by your doctor.
- If you or your child is also using inhaled or oral corticosteroids, you should never suddenly stop using that and replace it with MONTELUKAST BIOTECH therapy. Your doctor will advise how to gradually stop using the corticosteroids and when to introduce MONTELUKAST BIOTECH therapy.

### **What should you tell your doctor before you use MONTELUKAST BIOTECH?**

You need to tell your doctor about any medical problems or allergies that you or your child have now or had in the past.

### **Children and adolescents**

MONTELUKAST CHEW BIOTECH 4 chewable tablets are for use in children from 2 to 5 years old.

MONTELUKAST CHEW BIOTECH 5 chewable tablets are for use in children from 6 to 14 years old.

### **Other medicines and MONTELUKAST BIOTECH**

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

MONTELUKAST BIOTECH does not generally interfere with other medicine that you or your child may be taking. However, some medicine may affect how MONTELUKAST BIOTECH works or how it is excreted from the body, or MONTELUKAST BIOTECH may affect how your other medicine work or how it is excreted from the body. It is therefore very important to tell your doctor about all medicine that you or

your child are using or planning to use in the future, including those obtained without a prescription.

The following medicines should not be taken with MONTELUKAST BIOTECH:

- rifampicin (medicines for the treatment of tuberculosis)
- phenytoin and phenobarbital (medicine for the treatment of epilepsy)
- other non-steroidal anti-inflammatory medicine (such as aspirin)
- *St John's wort* (a natural anti-depressant).
  
- MONTELUKAST BIOTECH does not significantly change the activity of medicines such as theophylline (used to treat asthma, a tight chest), warfarin (used as a blood-thinning medicine), digoxin (used to treat heart conditions), oral contraceptives and corticosteroids such as prednisone or prednisolone (used to treat general inflammatory reactions in the body).
- MONTELUKAST BIOTECH does not significantly change the activity of medicines such as rosiglitazone and repaglinide (used to control high blood sugar in patients with type 2 diabetes) and paclitaxel (used in the treatment of certain cancers).
- Use of MONTELUKAST BIOTECH with gemfibrozil (used to treat high cholesterol) does not require any dosage adjustment, but an increase in adverse reactions may result and your doctor will monitor your treatment.
- Interactions with concurrent use of MONTELUKAST BIOTECH and trimethoprim (used to treat bacterial infections) are not expected.

### **MONTELUKAST BIOTECH with food, drink and alcohol**

MONTELUKAST BIOTECH can be taken with or without food.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please

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consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The safety of MONTELUKAST BIOTECH in pregnant or breastfeeding women has not been established.

MONTELUKAST BIOTECH should not be used during pregnancy and breastfeeding.

It is not known if MONTELUKAST BIOTECH is excreted in human milk.

### **Driving and using machines**

MONTELUKAST BIOTECH may cause side effects such as dizziness or drowsiness, which may affect your ability to drive.

It is not always possible to predict to what extent MONTELUKAST BIOTECH may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the driving a vehicle or operate machines until they are aware of the measure to which MONTELUKAST BIOTECH affects them.

### **MONTELUKAST CHEW BIOTECH contains aspartame**

This medicine contains aspartame in each MONTELUKAST CHEW BIOTECH tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **MONTELUKAST BIOTECH 10 contains lactose monohydrate and lecithin (soya)**

MONTELUKAST BIOTECH 10 tablets contain lactose.

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MONTELUKAST BIOTECH 10.
- MONTELUKAST BIOTECH 10 contains soya oil. If you are allergic to peanut or soya, do not use this medicine.

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- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take MONTELUKAST BIOTECH**

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

MONTELUKAST BIOTECH should always be taken exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about how or when to take MONTELUKAST BIOTECH.

Take MONTELUKAST BIOTECH once daily in the evening, with or without food, as your doctor has prescribed.

- The dosage for paediatric patients 2 to 5 years of age is one 4 mg chewable tablet daily.
- The dosage for paediatric patients 6 to 14 years of age is one 5 mg chewable tablet daily.
- The dosage for adults 15 years of age and older is one 10 mg film-coated tablet daily. The 10 mg film-coated tablet should be swallowed whole.

Talk to your doctor or pharmacist if you have the impression that the effect of MONTELUKAST BIOTECH is too strong or too weak.

#### **If you take more MONTELUKAST BIOTECH 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 MONTELUKAST BIOTECH**

If you or your child missed a dose, just resume the original schedule of one tablet once daily. Do not take a double dose to make up for the forgotten individual doses.

**If you stop taking MONTELUKAST BIOTECH**

It is important to continue taking MONTELUKAST BIOTECH for as long as your doctor prescribes it, even when you or your child is symptom free, in order to maintain control of you or your child's asthma.

**4. Possible side effects**

MONTELUKAST BIOTECH can have side effects.

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

If any of the following happens, stop taking MONTELUKAST BIOTECH 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to MONTELUKAST BIOTECH. You may need urgent medical attention or hospitalisation.

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

- seizure
- heartbeat being more noticeable and faster
- chest pain
- suicidal thoughts and behaviour
- aggressive behaviour, anxiousness, depression, irritability, restlessness
- abnormal dreams (including nightmares) and hallucinations
- yellowing of the skin and eyes, clay-coloured stools, dark urine, breath odour – an indication of liver disease

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- inflammation of the liver (hepatitis), with symptoms such as fatigue, loss of appetite and muscle or joint ache

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:

- upper respiratory tract infections (bronchitis, coughing)
- headache
- dizziness
- abdominal pain, diarrhoea
- gastroenteritis, dental pain
- indigestion, thirst
- skin rash
- feeling weak or tired, emotional stress (trauma)
- feeling unbalanced / spinning head

Less frequent side effects:

- an increased tendency of bleeding
- very low white blood cells, leaving the body vulnerable to serious infections
- low platelets in your blood causing bleeding into the tissues, bruising and slow blood clotting
- inflamed blood vessels leading to symptoms like asthma, sinus problems and organ damage
- porphyria (severe stomach pain, pain in your back and legs)
- insomnia (having difficulty sleeping), sleepwalking
- problems concentrating, memory loss, disorientation
- sudden, small, uncontrollable movement, esp. of the face, speech disorder such as stuttering

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- excessive thoughts (obsessions) that lead to repetitive behaviour (compulsions)
- drowsiness
- tingling or numbness in the hands and/or feet
- eye problems (abnormal contraction of the eyelid muscles, dilated pupils)
- cold or flu symptoms (blocked nose, coughing)
- nose bleeds
- inflammation of the lungs from an increase in eosinophils
- nausea, vomiting
- dry mouth, excessive production of saliva, flatulence
- skin disorders (e.g., itching, bruising, red lesions)
- skin condition that causes red, target-like lesions, often triggered by infections or certain medications.

It can lead to mild to moderate symptoms, including rash, fever, and discomfort. In severe cases, it may affect the mucous membranes, causing blistering and ulceration

- hives
- joint and/or muscle pain (including muscle cramps)
- bed-wetting usually in children
- increased sweating
- swelling in any part of the body, fever.
- changes in blood counts (picked up in blood tests).

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:

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<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MONTELUKAST BIOTECH.

## **5. How to store MONTELUKAST BIOTECH**

Store all medicine out of reach of children.

### **For how long should I keep my medicine?**

Do not use this medicine after the month and year following the expiry date printed on the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

### **How and where should I store my medicine?**

Store at room temperature at or below 25 °C, protected from moisture and light.

Keep blister in outer carton until required for use. Tablets should not be removed from blisters until required for use, to protect it from moisture.

## **6. Contents of the pack and other information**

### **What MONTELUKAST BIOTECH contains:**

MONTELUKAST BIOTECH contains montelukast as the active ingredient.

It is available as:

- a 10 mg tablet for adults and adolescents 15 years and older.
- a 5 mg chewable tablet for children 6 to 14 years old.
- a 4 mg chewable tablet for children 2 to 5 years old.

Each 4 mg chewable tablet contains 4 mg montelukast, each 5 mg chewable tablet contains 5 mg montelukast and each 10 mg film-coated tablet contains 10 mg montelukast.

In addition, MONTELUKAST BIOTECH tablets contain the following inactive ingredients:

MONTELUKAST CHEW BIOTECH 4 and 5 contains:

Mannitol, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, strawberry flavour,

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aspartame, red iron oxide, magnesium stearate.

MONTELUKAST BIOTECH 10 contains:

Croscarmellose sodium, lactose monohydrate, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, Opadry colourant (polyvinyl alcohol, titanium dioxide, talc, lecithin, xanthan gum, iron oxide yellow, iron oxide red), purified water.

### **What MONTELUKAST BIOTECH looks like and contents of the pack**

MONTELUKAST CHEW BIOTECH 4: A pink, oval biconvex tablet with “4” debossed in one side.

MONTELUKAST CHEW BIOTECH 5: A pink, round, biconvex tablet with “5” debossed in one side.

MONTELUKAST BIOTECH 10: A pale orange, round, biconvex tablet.

MONTELUKAST BIOTECH: is available in silver polyamide/Alu/PVC and silver aluminium blister packs of 28 and 30.

### **Holder of Certificate of Registration**

Biotech Laboratories (Pty) Ltd

Block K West, Central Park

400 16<sup>th</sup> Road, Halfway House

Midrand, 1685

Tel: (011) 848 3053

### **This leaflet was last revised in**

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### **Registration number**

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MONTELUKAST CHEW BIOTECH 4: 45/10.2.2/0475

MONTELUKAST CHEW BIOTECH 5: 45/10.2.2/0476

MONTELUKAST BIOTECH 10: 45/10.2.2/0477