APPROVED PATIENT INFORMATION LEAFLET:

BelAIR 4 & 5 mg (chewable tablets).

Read all of this leaflet carefully before you or your child starts to take BelAIR.

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

SCHEDULING STATUS:

S3

PROPRIETARY NAMES (AND DOSAGE FORMS)

BelAIR 4 (chewable tablets)

(4 mg montelukast)

BelAIR 5 (chewable tablets)

(5 mg montelukast)

WHAT BELAIR CONTAINS

BelAIR 4: Each chewable tablet contains 4 mg montelukast as montelukast sodium.

BelAIR 5: Each chewable tablet contains 5 mg montelukast as montelukast sodium.

BelAIR 4 & 5 chewable tablets also contain: aspartame, cherry flavour,

croscarmellose sodium, hydroxypropyl cellulose, iron oxide red, magnesium stearate, mannitol and microcrystalline cellulose.

WHAT BelAIR IS AND WHAT IT IS USED FOR

BelAIR is a leukotriene receptor antagonist. It works by blocking substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, **BelAIR** improves asthma symptoms and helps control asthma.

BelAIR is only available with your doctor's prescription.

Your doctor has prescribed **BelAIR** to treat your child's asthma, and to prevent asthma symptoms during the day and night. However, **BelAIR** should not be used to relieve an asthma attack that has already started.

BEFORE USING BelAIR

Do not give your child

- **BelAIR** if he/she is hypersensitive (allergic) to montelukast or any of the ingredients;
- **BelAIR** 4 mg if he/she is under the age of 2 years, as safety and efficacy have not been established in infants under this age;
- **BelAIR 5** if he/she is under the age of 6 years, as safety and efficacy have not been established in children under this age;

Do not take **BelAIR** if you are pregnant or breast-feeding.

Take special care with BelAIR

- You or your child should take **BelAIR** daily as prescribed, even when your symptoms are well controlled, as well as during periods of worsening asthma.
- You should contact your doctor if you or your childs asthma is not well controlled.
- **BelAIR** is not for the treatment of an acute attack of asthma. You should have appropriate inhalation medication available to treat worsening of asthma.
- You should seek medical attention if you or your child requires inhalation therapy more often than usual in a 24-hour period.
- You should not decrease the dose or stop medication prescribed for the treatment of your childs or your asthma, unless instructed by your doctor.
- If your asthma worsens during exercise, you should use your usual inhalation medication as prescribed for prevention of an asthma attack.
- If you are unaware that you or your child is sensitive to aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs such as ibuprofen) you should continue to avoid these medicines.
- **BelAIR** is used to prevent asthma attacks. It is not used to relieve an attack that has already started. For relief of an asthma attack that has already started, you should follow the instructions your doctor gave you for treating asthma attacks. Always have your inhaled rescue medicine for asthma attacks with you**.**
- To work properly, **BelAIR** must be taken every day at the same time, even if your child's asthma seems better.
- Do not stop taking **BelAIR**, even if your child's asthma seems better, unless you are told to do so by your doctor.

- If you or your child develop a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- The presence of other medical problems may affect the use of **BelAIR.**

Talk to your doctor, pharmacist or healthcare professional before taking **BelAIR** if you:

- are pregnant, trying to become pregnant, or breast-feeding;
- have a kidney or liver problem.
- Behaviour and mood-related changes have been reported: agitation including aggressive behaviour or hostility, bad/vivid dreams, depression, feeling anxious, hallucinations (seeing things that are not there), irritability, restlessness, sleep walking, suicidal thoughts and actions (including suicide), tremor, trouble sleeping. Tell your doctor if you or your child experience behaviour or mood-related changes while taking **BelAIR**.

Important information about some of the ingredients of BelAIR

BelAIR 4 & 5 chewable tablets contain aspartame, which is a source of phenylalanine. This may be harmful if your child has phenylketonuria (is an inherited disorder in which the body is unable to process phenylalanine).

Pregnancy and Breast-feeding

BelAIR should not be used if you are pregnant or breast-feeding.

Effects on the Ability to Drive or Operate Machinery

BelAIR may cause side-effects such as dizziness or drowsiness, which may affect the ability to drive. Patients should therefore be advised not to drive or operate machinery

until their individual susceptibility is known.

Taking BelAIR with food and drink

You can give **BelAIR** tablets to your child with or without food.

Using other medicines with BelAIR

If you or your child are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **BelAIR** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, nurse, or pharmacist.

If you or your child are taking any medicines containing the following:

- phenytoin or phenobarbital for epilepsy,
- rifampicin for tuberculosis;

please consult your doctor, pharmacist or other healthcare professional as these medicines may interact with **BelAIR.**

HOW TO USE BelAIR

Always give **BelAIR** to your child exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that **BelAIR** is too strong or too weak, you should talk to your doctor or pharmacist.

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

It is important to take **BelAIR** every day even during symptom-free periods.

Do not discontinue treatment without discussing it with your doctor.

Take **BelAIR** once daily in the evening with or without food:

BelAIR 4 Chewable tablet

Paediatric patients 2 to 5 years of age: One chewable tablet daily.

BelAIR 5 Chewable tablet

Paediatric patients 6 to 14 years of age: One chewable tablet daily.

What if your child forgot to take the tablets

If your child misses a dose of **BelAIR**, give it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

What if your child took too many tablets

You may experience an increase in side-effects and their frequency. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what your child have taken.

POSSIBLE SIDE-EFFECTS

BelAIR may cause side effects. Check with your doctor, pharmacist or healthcare professional if any of these side effects persist or become bothersome.

Contact a doctor immediately if you notice any of the following side-effects:

- Pus in the urine.
- Anaphylaxis (cough; difficulty swallowing; dizziness; fast heartbeat; hives; itching; puffiness or swelling of the eyelids or around the eyes, face, lips of tongue; shortness of breath; skin rash; tightness in chest; unusual tiredness or weakness; wheezing).
- angioedema (large, hive-like swelling on face, eyelids, lips, tongue, throat, hands, legs, feet, sex organs dark urine, light coloured stools).
- behaviour and mood-related changes (agitation including aggressive behaviour or hostility, bad/vivid dreams, depression, feeling anxious, hallucinations (seeing things that are not there), irritability, restlessness, sleep walking, suicidal thoughts and actions (including suicide), tremor, trouble sleeping).
- agitation (anxiety; nervousness; restlessness; irritability; dry mouth; shortness of breath; hyperventilation; trouble sleeping; irregular heartbeats; shaking).
- cholestatic hepatitis (abdominal or stomach pain; chills; clay-coloured stools; dark urine; diarrhoea; dizziness; fever; headache; itching; loss of appetite; nausea; rash; unpleasant breath odour; unusual tiredness or weakness; vomiting of blood; yellow eyes or skin).
- Hepatic eosinophilic infiltration (dark urine; general tiredness and weakness; light-coloured stools; nausea and vomiting; upper right abdominal pain; yellow eyes and skin).
- Pancreatitis (bloating; chills; constipation; darkened urine; fast heartbeat; fever; indigestion; loss of appetite; nausea; pains in stomach, side, or abdomen, possibly radiating to the back; vomiting; yellow eyes or skin).

- Palpitations (fast, irregular, pounding, or racing heartbeat or pulse).
- Seizures (convulsions or fits).
- Worsening of asthma symptoms.

Contact a doctor as soon as possible if any of the following side effects continue or become bothersome:

- Headache.
- Dizziness.
- Cough; stuffy nose; flu.
- Abdominal or stomach pain.
- Heartburn.
- Dental pain.
- Skin rash.
- A feeling of pins and needles or numbness of the arms and legs.
- Increased bleeding tendency; bruising.
- Joint pain; muscle aching or cramping; swelling.

Not all side-effects reported for **BelAIR** are included in this leaflet. Should your general health worsen while taking **BelAIR**, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION

Store in the original packaging. Keep blister packs in the carton until required for use.

Store at or below 25 °C.

Do not store your medicine in the bathroom.

Do not use BelAIR after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

PRESENTATION

BelAIR tablets are packed in packs of 28 (2 strips of 14 tablets or 4 strips of 7 tablets) or 30 (3 strips of 10 tablets) in blisters made of oPA/Al/PVC foil and Aluminium push through foil, in a cardboard carton.

IDENTIFICATION OF BelAIR

BELAIR 4: Pink, flat round tablets with bevelled edges, marked with '4' on one side and plain on the other, with a diameter of ± 7, 1 mm.

BELAIR 5: Pink, flat round tablets with bevelled edges, with a diameter of ± 8, 1 mm.

REGISTRATION NUMBERS

BelAIR 4: 45/10.2.2/0744

BelAIR 5: 45/10.2.2/0745

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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