FINAL PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking BELAIR 10 mg:

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **BELAIR 10 mg** 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.

Schedule 3

BELAIR 10 mg (film-coated tablet)

Montelukast

WHAT BELAIR 10 mg (film-coated tablet) CONTAINS:

The active substance is montelukast.

The other ingredients are:

Microcrystalline cellulose (Type PH 112), lactose monohydrate, croscarmellose sodium, low-substituded hydroxypropyl cellulose (Type LH-11), magnesium stearate, Opadry Orange.

WHAT BELAIR 10 mg (film-coated tablet) IS USED FOR:

BELAIR 10 mg blocks substances called leukotrienes, that cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks in adults and children 15 years or older.

BEFORE YOU TAKE OR GIVE BELAIR 10 mg (film-coated tablet):

Do not take BELAIR 10 mg (film-coated tablet) if:

- You are hypersensitive (allergic) to montelukast or any of the other ingredients of **BELAIR 10 mg**
- You are pregnant or breast-feeding
- You are under the age of 15 years.

Take special care with BELAIR 10 mg (film-coated tablet):

- Even if you have no symptoms or an asthma attack, you should continue taking **BELAIR 10 mg** daily as prescribed by your doctor
- If your asthma symptoms get worse, you should contact your doctor immediately
- If you find that you need to use your inhaled rescue medicine for asthma attacks more often than usual, you should contact your doctor immediately
- Oral tablets of **BELAIR 10 mg** are not for the treatment of acute asthma attacks. If an attack occurs, you should follow the instructions your doctor has given you for that situation
- If your asthma symptoms become worse after exercise, you should continue using the inhaled rescue medicine before exercising to prevent asthma attacks
- If your asthma is known to be made worse by aspirin, do not take aspirin and other non-steroidal anti-inflammatory medicines such as ibuprofen
- If you develop a combination of symptoms such as flu-like illness, pins and needles or numbness of your arms and legs, worsening of lung symptoms, and/or rash you should tell your doctor immediately

- Tell your doctor about any medical problems or allergies you have now or have had
- If you require inhalation therapy more often than usual in a 24-hour period you should seek medical attention
- You should not decrease the dose or stop any medication prescribed for the treatment of your asthma, unless instructed by your doctor

Hypersensitivity to aspirin

If you have known aspirin sensitivity, avoid taking aspirin or non-steroidal anti-inflammatory medicines while taking **BELAIR 10 mg**.

Pregnancy and Breast-feeding:

If you are pregnant or breast-feeding your baby, do not take **BELAIR 10 mg**. Consult your doctor or pharmacist for advice.

Driving and using machinery:

BELAIR 10 mg may cause you to feel drowsy or dizzy which may affect your ability to drive a car or operate machinery, safely. You are therefore advised not to drive or operate machinery until you know whether you are susceptible or not to **BELAIR 10 mg**.

Important Information about some of the ingredients of BELAIR 10 mg:

Galactose intolerance:

BELAIR 10 mg tablets contain lactose. If you suffer with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose

malabsorption do not take **BELAIR 10 mg**.

Taking other medicines with BELAIR 10 mg (film-coated tablet):

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **BELAIR 10 mg** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are using any of the following medicines, before taking **BELAIR 10 mg**:

- phenobarbital (used for the treatment of epilepsy)
- phenytoin (used for the treatment of epilepsy)

rifampicin, itraconazole, ketoconazole (used for the treatment of certain infections like tuberculosis) and ritonavir (used for the treatment of patients with HIV infection).

BELAIR 10 mg may interfere with other medicines that you may be taking. It is important, therefore, to tell your doctor about all medicines or supplements that you are using or plan to use, including those obtained without a prescription.

HOW TO TAKE BELAIR 10 mg (film-coated tablet):

Montelukast 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 use your usual rescue medicine as prescribed by your doctor.

Adults and Adolescents ≥ 15 years of age (and older):

The dose for the treatment of asthma is one 10 mg tablet daily, in the evening with or without food, as your doctor has prescribed.

Always take **BELAIR 10 mg** 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 the effect of **BELAIR 10 mg** is to strong or too weak, talk to your doctor or pharmacist.

It is important to continue taking **BELAIR 10 mg** for as long as your doctor prescribes it in order to maintain control of your asthma. **BELAIR 10 mg** can treat your asthma only if you continue to take it.

BELAIR must not be taken or given to children under the age of 15 years.

If you take more BELAIR 10 mg (film-coated tablet) than you should:

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

If you forget to take BELAIR 10 mg (film-coated tablet):

Try to take **BELAIR 10 mg** as prescribed.

However. If you miss a dose, just resume the usual schedule of one tablet once daily. Do not take a double dose to make up for the forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

BELAIR 10 mg can have side effects.

If any of the following occur, stop taking **BELAIR 10 mg** and speak to your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of asthma symptoms and/or rash
- bruising, itching, hives, tender red lumps under the skin most commonly on your shins (erythema nodosum).

These are all very serious side-effects if you have them you may have had a serious allergic reaction to **BELAIR 10 mg**.

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

- behaviour and mood related changes (dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, tremor, depression, inability to sleep, sleep walking, suicidal thoughts and actions)
- palpitations
- increased bleeding tendency
- seizures.

Tell your doctor if any of the following side-effects continue or become bothersome:

- Headache
- Stomach pain
- Fever
- Skin rash
- Heartburn

- Diarrhoea
- Stuffy nose
- Cough
- Weakness or unusual tiredness
- Dizziness
- Bodily injury (trauma).

Not all side effects reported for this medicine are included in this leaflet.

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

Should your general health worsen while taking this medicine, please contact your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF BELAIR 10 mg:

Do not use the medicine after the expiring date printed on the carton.

Return all unused medicine to your pharmacist.

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

Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.

Store at room temperature at or below 25 ˚C, protected from light

Keep the blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF BELAIR 10 mg (film-coated tablet):

The tablets are blister packed in Opaque PA-AL-PVC/Alu foil blisters, one side bright and the other side dull. Each pack contains 28 or 30 tablets, containing 2 blister strips of 14 tablets or 3 blister strips containing 10 tablets.

Not all pack sizes are necessarily marketed.

IDENTIFICATION OF BELAIR 10 mg (film-coated tablet):

BELAIR 10 mg: A beige, square shape, biconvex film-coated tablets, marked ***MOK10*** on one face and ***PHD471*** on the other face.

REGISTRATION NUMBER

44/10.2.2/0431

NAME AND ADDRESS OF REGISTRATION HOLDER

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