

Proprietary name:	MONTELUKAST ALKEM
Dosage form:	Film-coated tablets
Active Ingredient:	Montelukast sodium equivalent to Montelukast
Strength per dosage unit:	10 mg per tablet

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

Montelukast Alkem 10 mg Film-coated tablets

Montelukast sodium

Contains sugar:

Each film-coated tablet contains 89.000 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking Montelukast Alkem.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **Montelukast Alkem** 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 Alkem is and what it is used for
2. What you need to know before you take Montelukast Alkem
3. How to take Montelukast Alkem
4. Possible side effects
5. How to store Montelukast Alkem
6. Contents of the pack and other information

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1. WHAT Montelukast Alkem IS AND WHAT IT IS USED FOR:

Montelukast Alkem is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, **Montelukast Alkem** improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor will determine how **Montelukast Alkem** should be used depending on the symptoms and severity of your asthma.

Asthma includes:

- difficulty in breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of airways.
- Coughing, wheezing, and chest tightness.

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically include stuffy, runny, itchy nose; sneezing; watery, swollen and red, itchy eyes.

Your doctor has prescribed **Montelukast Alkem** to treat asthma, preventing your asthma symptoms during the day and night.

- **Montelukast Alkem** is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- **Montelukast Alkem** also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom **Montelukast Alkem** is indicated in asthma, **Montelukast Alkem** can also provide symptomatic relief of seasonal allergic rhinitis.

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2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Montelukast Alkem

Do not take Montelukast Alkem:

- if you are allergic (hypersensitive) to montelukast or any of the other ingredients of **Montelukast Alkem** (listed in section 6: contents of the package and other information),
- if you currently under the age of 15 years,

Warnings and precautions

Special care should be taken with **Montelukast Alkem**.

If your asthma or breathing gets worse, tell your doctor immediately.

Oral **Montelukast Alkem** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.

It is important that you take all asthma medications prescribed by your doctor. **Montelukast Alkem** should not be substituted for other asthma medications your doctor has prescribed for you.

Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.

You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Children and adolescents

Montelukast Alkem is not to be used in children below 15 years of age.

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Other medicines and Montelukast Alkem

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

Some medicines may affect how **Montelukast Alkem** works, or **Montelukast Alkem** may affect how other medicines work.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Tell your doctor if you are taking the following medicines before starting **Montelukast Alkem**:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma)

You should also tell any doctor who is prescribing a new medicine for you that you are taking **Montelukast Alkem**.

Montelukast Alkem with food and drink

Montelukast Alkem may be taken with or without water.

Pregnancy and breast-feeding

Do not take **Montelukast Alkem** if you are pregnant.

Do not take **Montelukast Alkem** if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

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Driving and using machines

Montelukast Alkem is not expected to interfere with your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported rarely with **Montelukast Alkem** may affect some patients' ability to drive or operate machinery.

Montelukast Alkem contains lactose

Montelukast Alkem contains a sugar called lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **Montelukast Alkem**.

3. HOW TO TAKE Montelukast Alkem

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

Always take **Montelukast Alkem** exactly as your doctor has instructed you.

You should take only one tablet of **Montelukast Alkem** once a day as prescribed by your doctor.

It should be taken even when you have no symptoms or have an acute asthma attack.

You should check with your doctor or pharmacist if you are not sure.

For adults 15 years of age and older:

One 10 mg tablet to be taken daily in the evening. **Montelukast Alkem** may be taken with or without food.

If you are taking **Montelukast Alkem**, be sure that you do not take any other products that contain the same active ingredient, montelukast.

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If you take more Montelukast Alkem than you should

Please contact your doctor or pharmacist immediately.

The frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to take Montelukast Alkem

Try to take **Montelukast Alkem** 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 a forgotten tablet.

If you stop taking Montelukast Alkem

Montelukast Alkem can treat your asthma only if you continue to take it.

It is important to continue taking **Montelukast Alkem** for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Montelukast Alkem can have side effects, although not everybody gets them.

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

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

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing

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

Tell your doctor if you notice the following:

Frequent side effects:

- rash, fever, headache, passing loose watery stools (diarrhoea), feeling sick (nausea) and vomiting
- upper respiratory tract infections (infection of nose, throat and airways)
- possible liver problems (due to elevated enzymes on tests)

Less frequent side effects:

- abdominal pain, heartburn, thirst, dry mouth, and other stomach problems.
- dizziness, and fits
- increased bleeding tendencies; lowered white blood cell count, nosebleed (epistaxis).
- behaviour and mood related changes (dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression; tremor, disturbance in attention, memory impairment; hallucinations, disorientation, suicidal thoughts and actions)
- muscle pain
- Churg-Strauss syndrome (symptoms include fatigue, weight loss, nasal passage inflammation, numbness, and weakness)
- heart palpitations
- inflammation of the liver (hepatitis)
- bruising, itching, increased sweating, swelling of the skin
- feeling weak and tired, feeling sick, general swelling

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

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Reporting of side effects:

If you get side effects, talk to your doctor or, 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 Montelukast Alkem.

Alternatively, all adverse events can be reported to Ascend Laboratories via the e-mail: pharmacist.rsa@Alkem.com.

5. HOW TO STORE Montelukast Alkem

Store at or below 25 °C (Room temperature).

Store in the original package. Keep the blisters in the outer carton.

Keep this medicine out of reach of children.

Do not use this medicine after the expiry date stated on the carton and the blister.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Montelukast Alkem contains:

The active ingredient is 10 mg of montelukast sodium per film-coated tablet.

The other ingredients are Croscarmellose sodium, hydroxypropyl cellulose; lactose monohydrate, magnesium stearate, microcrystalline cellulose, and coating solution, Opadry yellow 03B52874 (hydroxypropyl methylcellulose, iron oxide red, iron oxide yellow and polyethylene glycol).

What Montelukast Alkem looks like and contents of the pack

Beige coloured, square shaped, biconvex, film coated tablets plain on both sides.

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Pack sizes: 14 tablets

Holder of Certificate of Registration

Ascend Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion, 0157

This leaflet was last revised in

Application Numbers

530068

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.