

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LEUKOBLOK 4 mg (chewable tablets)

LEUKOBLOK 5 mg (chewable tablets)

LEUKOBLOK 10 mg (film-coated tablets)

Montelukast

Contains aspartame and mannitol.

Read all of this leaflet carefully before you give this medicine to your child or you start taking LEUKOBLOK

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

1. What LEUKOBLOK is and what it is used for

LEUKOBLOK contains the active ingredient montelukast that belongs to a group of medicines called leukotriene receptor antagonists. It helps to block substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, LEUKOBLOK improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis). Asthma is a condition in which your airways narrow and swell and may produce extra mucus.

LEUKOBLOK 4 mg chewable tablets are used in children 2 to 5 years old for the prevention and treatment of asthma.

LEUKOBLOK 5 mg chewable tablets are used in children 6 to 14 years old for the prevention and treatment of asthma.

LEUKOBLOK 10 mg film-coated tablets are used in adults and children 15 years of age and older. LEUKOBLOK may provide some symptomatic relief of seasonal allergic rhinitis (hay fever) in those adult asthmatic patients, in whom LEUKOBLOK is indicated in asthma.

2. What you need to know before you take LEUKOBLOK

Do not take or give your child LEUKOBLOK

- If you or your child are allergic to montelukast or any of the other ingredients of LEUKOBLOK (listed in section 6).

Do not give your child LEUKOBLOK 4 mg to take

- If he/she is under the age of 2 years, as safety and efficacy have not been demonstrated.

Warnings and precautions

Tell your doctor, pharmacist or other healthcare provider if you or your child has medical problems or allergies.

Take special care with LEUKOBLOK

- It is important that you or your child take all asthma medication prescribed for you by your doctor. LEUKOBLOK should not be substituted for other asthma medications your doctor has prescribed for you.
- LEUKOBLOK is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or for your child for that situation. Always have your or your child's emergency asthma pump for asthma attacks with you.
- If you or your child's asthma symptoms gets worse, or if you need to increase the use of your or your child's emergency asthma pump or if it needed more often for asthma attacks you should contact your doctor immediately.
- If your doctor has prescribed a medicine for you or your child to use before exercise, keep using that medicine and have a rescue medicine e.g. asthma pump available.
- It is important that you or your child continue taking LEUKOBLOK daily as prescribed by your doctor, even when you or your child have no symptoms.
- 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 lung symptom, and/or rash, you should tell your doctor immediately.
- If your or your child's asthma is known to be made worse by aspirin, do not take aspirin or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs such as ibuprofen or diclofenac).
- If you or your child develop any symptoms of for example behaviour and mood-related changes while taking LEUKOBLOK, you should tell your doctor (see section 4).

- If you or your child has a condition called phenylketonuria, you should tell your doctor, pharmacist or healthcare provider. LEUKOBLOK tablets contain a sweetener called aspartame which is a source of phenylalanine.

If you are not sure, talk to your doctor or pharmacist before taking LEUKOBLOK.

Other medicines and LEUKOBLOK

Always tell your doctor, pharmacist or other health care professional if you are taking any other medicine (this includes all complementary or traditional medicines).

In general, LEUKOBLOK does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how LEUKOBLOK works, or LEUKOBLOK may affect how other medicines work.

Tell your doctor if you are taking the following medicines before starting LEUKOBLOK:

- 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 fat levels in your blood)

LEUKOBLOK with food and drink

LEUKOBLOK may be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while taking this medication, please consult your doctor, pharmacist or other health care professional for advice.

The safety of LEUKOBLOK in pregnant and breastfeeding women has not been established.

Driving and using machines

LEUKOBLOK is not expected to affect 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 with LEUKOBLOK may affect some patients' ability to drive or operate machinery.

LEUKOBLOK contains aspartame

LEUKOBLOK contains aspartame (0,6 mg per 4 mg chewable tablet; 0,743 mg per chewable tablet and 1,5 mg per 10 mg film-coated tablet respectively). Aspartame is a sweetener taken as a substitute for sugar which is metabolised to a substance called phenylalanine.

If you or your child have a condition called phenylketonuria you should tell your doctor, pharmacist or other healthcare professional as LEUKOBLOK should be used with caution in patients with this condition.

3. How to take LEUKOBLOK

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For children 2 to 5 years of age the usual dose is one 4 mg chewable tablet daily to be taken in the evening.

For children 6 to 14 years of age the usual dose is one 5 mg chewable tablet daily to be taken in the evening.

LEUKOBLOK 4 mg and 5 mg is for oral use and must be chewed before swallowing.

For adults and adolescents 15 years of age and older the usual dose is one 10 mg tablet to be taken daily in the evening. LEUKOBLOK 10 mg is for oral use.

If you have the impression that the effect of LEUKOBLOK is too strong or too weak, talk to your doctor or pharmacist.

If you take more LEUKOBLOK than you should

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

The most frequently occurring symptoms reported with overdosage in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, psychomotor hyperactivity (including irritability, restlessness, uncontrolled muscle movements).

If you or your child forgets to take LEUKOBLOK

If you or your child misses a dose, do not take a double dose to make up for the forgotten individual doses. Resume the usual schedule of one tablet once daily.

If you stop taking LEUKOBLOK

It is important for you or your child to continue taking LEUKOBLOK for as long as your doctor prescribes it in order to maintain control of your or your child's asthma. LEUKOBLOK can treat your or your child's asthma only if you continue to take it.

4. Possible side effects

LEUKOBLOK can have side effects.

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

If any of the following happens, stop taking LEUKOBLOK and tell your doctor immediately or go to the casualty department of 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
- fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to LEUKOBLOK. You 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:

- suicidal thoughts and actions
- seizures.

Tell your doctor if you notice any behaviour and mood-related changes that have been reported with the use of LEUKOBLOK:

- abnormal dreams
- seeing, hearing or seeing things that are not there
- agitation including aggressive behaviour
- depression
- feeling anxious
- inability to sleep
- irritability, restlessness
- uncontrolled muscle movements

Side effects that are reported frequently include

- headache
- abdominal pain
- thirst

Other side effects that you or your child might experience while you take LEUKOBLOK

Frequent side effects:

- upper respiratory infection
- diarrhoea, nausea, vomiting
- elevated liver enzymes
- rash
- fever

Less frequent side effects:

- increased bleeding tendency, low blood platelet count
- hypersensitivity (allergic) reactions
- behaviour and mood related changes, nightmares, trouble sleeping, sleepwalking, attention problems, forgetfulness, disorientation, obsessive-compulsive symptoms, stuttering
- dizziness, drowsiness, pins and needles/numbness
- irregular heartbeat (palpitations)
- nosebleed, inflammation of blood vessels and swelling (inflammation) of the lungs
- dry mouth, indigestion
- inflammation of the liver (hepatitis)
- bruising, itching, hives, swelling, tender red lumps under the skin, most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome)

(see section 2)

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or healthcare provider. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form” found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LEUKOBLOK.

5. How to store LEUKOBLOK

Store at room temperature below 30 °C, store in the original packaging to protect from light and moisture.

Do not use LEUKOBLOK after the expiry date which is stated on the carton.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What LEUKOBLOK contains

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

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

LEUKOBLOK 10 mg: Each film-coated tablet contains 10 mg montelukast as montelukast sodium.

The other ingredients are:

LEUKOBLOK 4 mg and LEUKOBLOK 5 mg: Mannitol (spray dried), croscarmellose sodium, aspartame, banana flavour, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, iron oxide red (E172) and magnesium stearate.

LEUKOBLOK 10 mg: Mannitol (spray dried), croscarmellose sodium, aspartame, cherry flavour, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, iron oxide red (E172) and magnesium stearate. Film-coating: Hypromellose 3cP, hydroxypropylcellulose, talc, titanium oxide (E 171), iron oxide yellow (E172), iron oxide red (E172).

What LEUKOBLOK looks like and contents of the pack

LEUKOBLOK 4 mg chewable tablets: Pink, flat round, tablets with bevelled edges, marked with '4' on one side and plain on the other.

LEUKOBLOK 5 mg chewable tablets: Pink, flat round, tablets with bevelled edges.

LEUKOBLOK 10 mg film-coated tablets: Beige, round, biconvex film-coated tablets.

LEUKOBLOK tablets are available in aluminium/aluminium blister packs of 28 or 30. Not all pack sizes may be marketed.

Holder of certificate of registration

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7570

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