

Read all of this leaflet carefully before you start giving this medicine to your child because it contains important information for you. Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's. If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.



AVADIL 5 mg
Montelukast

What is in this leaflet

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1. What **AVADIL 5 mg** is and what it is used for

AVADIL 5 mg (montelukast) is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, **AVADIL 5 mg** improves asthma symptoms and helps control asthma.

Asthma is a long-term disease.

Asthma includes:

- difficulty 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, or cold air, or exercise.
- swelling (inflammation) in the lining of airways.

Symptoms of asthma include: coughing, wheezing, and chest tightness.

Your doctor has prescribed **AVADIL 5 mg** to treat your child's asthma, preventing asthma symptoms during the day and night.

AVADIL 5 mg is used for the treatment of 6 to 14 year old patients who are not adequately controlled on their medication and need additional therapy.

AVADIL 5 mg may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

AVADIL 5 mg also helps prevent the narrowing of airways triggered by exercise for 6 year old patients and older.

Your doctor will determine how **AVADIL 5 mg** should be used depending on the symptoms and severity of your child's asthma.

2. What you need to know before you give **AVADIL 5 mg** to your child

Tell your doctor about any medical problems or allergies your child has now or has had.

Do not give **AVADIL 5 mg** to your child:

- if your child is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before giving **AVADIL 5 mg** to your child:

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral **AVADIL 5 mg** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your child's inhaled rescue

medicine for asthma attacks with you.

- It is important that your child uses all the asthma medication prescribed by the doctor. **AVADIL 5 mg** should not be used instead of other asthma medications your doctor has prescribed to your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops 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.
- Your child should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

Other medicines and **AVADIL 5 mg**

Some medicines may affect how **AVADIL 5 mg** works, or **AVADIL 5 mg** may affect how your child's other medicines work. Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Tell the doctor if your child is taking the following medicines before starting **AVADIL 5 mg**

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections).

AVADIL 5 mg with food

AVADIL 5 mg should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

Pregnancy

This subsection is not applicable for the **AVADIL 5 mg** since it is intended for use in children from 6 to 14 years of age, however the following information is relevant to the active ingredient, montelukast. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will assess whether you can take montelukast during this time.

Breast-feeding

It is not known if montelukast appears in breast-milk. You should consult your doctor before taking montelukast if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the **AVADIL 5 mg** since they are intended for use in children from 6 to 14 years of age, however the following information is relevant to the active ingredient, montelukast. Montelukast 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 very rarely with montelukast may affect some patients' ability to drive or operate machinery.

Important informations about some ingredients in **AVADIL 5 mg**

AVADIL 5 mg contains mannitol. Mannitol can cause a laxative effect.

3. How to take **AVADIL 5 mg**

Your child should take only one tablet of **AVADIL 5 mg** once a day as prescribed by your doctor.

- It should be taken even when your child has no symptoms

or has an acute asthma attack.

- Always have your child take this medicine exactly as your doctor has told you.
- To be taken by mouth

Use in children 6 to 14 years of age

One 5 mg chewable tablet daily to be taken in the evening.

AVADIL 5 mg should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food. If your child is taking **AVADIL 5 mg**, be sure that he/she does not take any other medicine that contains the same active ingredient, montelukast.

Use in children 2 to 5 years old

AVADIL 5 mg is not recommended for children below 6 years of age. Dosage for children of this age group is 4 mg. Montelukast is not recommended for children below 2 years of age.

If your child takes more AVADIL 5 mg than he/she should

Contact your doctor immediately for advice. There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to give AVADIL 5 mg to your child

Try to give **AVADIL 5 mg** as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet once daily. Do not give a double dose to make up for a forgotten dose.

If your child stops taking AVADIL 5 mg

AVADIL 5 mg can treat your child's asthma only if you or your child continues to take it. It is important to continue taking **AVADIL 5 mg** for as long as your doctor prescribes. It will help control your child's asthma. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with montelukast 5 mg, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to montelukast were:

- headache

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets:

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention:

- Very common (affects at least 1 user in 10)
- Common (affects 1 to 10 users in 100)
- Uncommon (affects 1 to 10 users in 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Very rare (affects less than 1 user in 10,000)

Additionally, while the medicine has been on the market, the following have been reported:

- upper respiratory infection (*very common*)
- increased bleeding tendency (*Rare*)
- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (*Uncommon*)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (*Uncommon*); tremor, disturbance in attention, memory impairment (*Rare*); hallucinations, disorientation, suicidal thoughts

and actions (*Very rare*)]

- dizziness, drowsiness, pins and needles / numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, nausea, vomiting (*Common*); dry mouth, indigestion (*Uncommon*)
- hepatitis (inflammation of the liver) (*Very rare*)
- rash (*Common*); bruising, itching, hives (*Uncommon*); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); weakness/tiredness, feeling unwell, swelling (*Uncommon*).

In asthmatic patients treated with montelukast, very rare cases of a 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) have been reported. You must tell your doctor right away if you get one or more of these symptoms. Ask your doctor or pharmacist for more information about side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store AVADIL 5 mg

Do not store above 30°C. Store in the original package. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What AVADIL 5 mg contains?

- The active substance is montelukast. Each chewable tablet contains 5 mg montelukast (as montelukast sodium).
- The other ingredients are: mannitol (E421), microcrystalline cellulose, croscarmellose sodium, magnesium stearate, vanillin, sodium saccharin, red iron oxide (E172), titanium dioxide (E171).

What AVADIL 5 mg looks like and contents of the pack?

Cardboard box with 30 chewable tablets, round-shaped, pink, in a blister packs (3 blister x 10 tablets).

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals Ltd.
Donji Bistarac bb
75300 Lukavac, Bosnia and Herzegovina.

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Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:

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