

Package leaflet: Information for the user

Montelukast Stada 5 mg chewable tablets For children from 6 to 14 years

Montelukast

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you or your child.

- 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 you or 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 or your child's.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Montelukast Stada 5 mg is and what it is used for
2. What you need to know before you take Montelukast stada 5 mg
3. How to take Montelukast Stada 5 mg
4. Possible side effects
5. How to store Montelukast Stada 5 mg
6. Contents of the pack and other information

1. What Montelukast Stada 5 mg is and what it is used for

What is

Montelukast Stada is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelukast Stada works

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast Stada improves asthma symptoms and helps control asthma.

When Montelukast Stada should be used

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

- Montelukast Stada is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- Montelukast Stada 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.
- Montelukast Stada also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Montelukast Stada should be used depending on the symptoms and severity of your or your child's asthma.

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

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

2. What you need to know before you take Montelukast Stada 5 mg

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

DO NOT take Montelukast Stada

- If you are or 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 you or your child are taking Montelukast Stada

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Stada is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast Stada should not be used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should be aware that if you 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.
- You or your child 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.

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If you or your child develop such symptoms while taking montelukast, you should contact your or your child's doctor.

Children and adolescents

Do not give this medicine to children less than 6 years of age. There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

Other medicines and Montelukast Stada

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Some medicines may affect how Montelukast Stada works, or Montelukast Stada may affect how other medicines work. Tell your doctor if you or your child are taking the following medicines before starting Montelukast Stada:

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

Montelukast Stada with food and drink

Montelukast Stada 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

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.

Pregnancy

Your doctor will assess whether you can take this medicine during this time.

Breast-feeding

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

Driving and using machines

Montelukast Stada 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 montelukast may affect some patients' ability to drive or operate machinery.

Montelukast Stada contains aspartame (E951)

This medicine contains 6 mg aspartame in each chewable tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Montelukast Stada contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.

3. How to take Montelukast Stada 5 mg

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

- You or your child should take only one chewable tablet of Montelukast Stada once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

For children 6 to 14 years of age:

The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.

If you or your child are taking Montelukast Stada, be sure that you or your child do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Montelukast Stada 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Montelukast Stada

If you or your child take more Montelukast Stada than you 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 take Montelukast Stada or give Montelukast Stada to your child

Try to take Montelukast Stada as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking Montelukast Stada

Montelukast Stada can treat you or your child's asthma only if you or your child continues to take it.

It is important to continue taking Montelukast Stada for as long as your doctor prescribes. It will help control you or 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 chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast Stada 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).

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects with your child, which may be serious, and for which your child may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure

Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- 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)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Montelukast Stada 5 mg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and outer package. The expiry date refers to the last day of that month.

Store in the original package, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Montelukast Stada contains

The active substance is: montelukast (as montelukast sodium).
One chewable tablet contains montelukast sodium, which is equivalent to 5 mg montelukast.

The other ingredients are:

Microcrystalline cellulose, mannitol, crospovidone type B, red iron oxide (E172), hydroxypropylcellulose, disodium edetate, cherry flavour, aspartame (E951), talc, magnesium stearate.

What Montelukast Stada looks like and contents of the pack

Montelukast Stada 5 mg chewable tablets are pink, round, biconvex tablets with "M5" engraved on one side.

Montelukast Stada is available in packs sizes of

Nylon/Alu/PVC - Aluminium/ blisters:

blister (without weekdays indicated): 10, 20, 30, 50, 60, 90, 100 and 250 tablets

blister (without weekdays indicated): 7, 14, 28, 56, 98, 126 and 154 tablets

HDPE bottles:

10, 20, 30, 50, 60, 90, 100 and 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally.]

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
LAMP SANPROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero (Modena)
Italy

Eurogenerics NV/SA, Heizel Esplanade b22, 1020 Brussel, Belgium
STADA Arzneimittel GmbH, Muthgasse 36 , 1190 Wien, Austria (only 1720)
HBM Pharma s.r.o., Sklabinská 30, 036 80 Martin, Slovakia
Saneca Pharmaceutical a.s., Nitrianska 100, 920 27 Hlohovec, Slovak Republic
Laboratori Fundació Dau Calle Lletra C de la Zona Franca 12-14, Polígono Industrial de la
Zona Franca de Barcelona, 08040, Barcelona

This medicinal product is authorised in the Member States of the EEA under the following names:

AT: Montelukast STADA 5 mg Kautabletten
BE: Montelukast Eurogenerics 5 mg kauwtabletten

DK: Montelukast Stada
ES: MONTELUKAST STADA 5 mg comprimidos masticables EFG
FR: MONTELUKAST EG 5 mg comprimé à croquer

IE: Montelair 5 mg chewable tablets

LU: Montelukast Eurogenerics 5 mg comprimé à croquer

PT: Montelucaste Ciclum

SE: Montelukast STADA, 5 mg tuggtablett

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