

Package leaflet: Information for the user

Montelukast Pensa 4 mg chewable tablets
Montelukast

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your child's 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.
- If you get any side effects, talk to your child's 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 Pensa is and what it is used for
2. What you need to know before your child takes Montelukast Pensa
3. How to take Montelukast Pensa
4. Possible side effects
5. How to store Montelukast Pensa
6. Contents of the pack and other information

1. What Montelukast Pensa is and what it is used for

Montelukast Pensa is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast Pensa improves asthma symptoms and helps control asthma.

Your child's doctor has prescribed Montelukast Pensa to treat your child's asthma, preventing the asthma symptoms during the day and night.

- Montelukast Pensa is used for the treatment of 2 to 5 years old patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast Pensa may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 years old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- Montelukast Pensa also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your child's doctor will determine how should be used depending on the symptoms and severity of 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 your child takes Montelukast Pensa

Do not use Montelukast Pensa:

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

Warnings and precautions

Tell your child's doctor or pharmacist before using

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

Children

For children 2 to 5 years old, Montelukast Pensa 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast Pensa 5 mg chewable tablets are available.

Other medicines and Montelukast Pensa

Tell your child's doctor or pharmacist if your child is taking, have recently taken or might take in other medicines.

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

Tell the doctor if your child is taking the following medicines before starting Montelukast Pensa:

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

Montelukast Pensa with food, drink and alcohol

Montelukast Pensa should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Pregnancy, breast feeding and fertility

This section is not applicable for Montelukast Pensa since it is intended for use in children of 2 to 5 years old. 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.

Use in pregnancy

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

Use in breast-feeding

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

Driving and using machines

This section is not applicable for Montelukast Pensa since it is intended for use in children of 2 to 5 years old. However the following information is relevant to the active ingredient, montelukast.

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

This medicinal product contains aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Montelukast Pensa

Always give to your child this medicine exactly as your child's doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

- Your child should take only one tablet of Montelukast Pensa once a day as prescribed by the doctor.
- It should be taken even when your child has no symptoms or has an acute asthma attack.
- To be taken by mouth

Use in children 2 to 5 years of age:

One Montelukast Pensa 4 mg chewable tablet daily to be taken in the evening. Montelukast Pensa 4 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If your child is taking Montelukast Pensa be sure that your child does not take any other products that contain the same active ingredient, montelukast.

Use in children

For children 2 to 5 years old, Montelukast Pensa 4 mg chewable tablets are available.
For children 6 to 14 years old, Montelukast Pensa 5 mg chewable tablets are available.
Montelukast Pensa 4 mg chewable tablet is not recommended below 2 years of age.

If your child takes more Montelukast Pensa than he/she should

Contact your child's 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 Montelukast Pensa to your child

Try to give Montelukast Pensa as prescribed. However, if 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 Montelukast Pensa

Montelukast Pensa can treat your child's asthma only if your child continues to take it. It is important to continue giving Montelukast Pensa for as long as the doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's 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 4 mg chewable tablets, 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:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets and 5 mg chewable tablets:

- headache

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 (*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*); 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 your child gets one or more of these symptoms.

Reporting of side effects

If your child gets any side effects, talk to the doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via e-mail to imbpharmacovigilance@imb.ie, or via mail to Pharmacovigilance Section Irish Medicines Board Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2, or by telephone or fax: Tel: +353 1 6764971, Fax: +353 1 6767836.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Montelukast Pensa

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

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light and moisture.

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.

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 Pensa contains

The active substance is montelukast. Each tablet contains 4 mg of montelukast (as sodium salt).

The other ingredients are: cellulose microcrystalline, mannitol (E-421), sodium croscarmellose, aspartame (E-951), red iron oxide (E-172), magnesium stearate (E-572), cherry flavor (maltodextrin starch, modified food (waxy maize), artificial flavors, triacetin, benzyl alcohol).

What Montelukast Pensa looks like and contents of the pack

The 4 mg chewable tablets are pink and biconvex with the code M4 engraved on one side.

The chewable tablets are provided in blister packs containing 14, 28 and 98 chewable tablets. Some pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pensa Pharma AB
Birger Jarlsgatan 22
114 34 Stockholm
Sweden

Manufacturer

Idifarma Desarrollo Farmaceutico, S.L.

Polígono Moncholí, C/ Noáin, N° 1,
Noáin, 31110 Navarra
SPAIN

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

Country	Name
ES, IE, IT, SE	Montelukast Pensa
PT	Montelucaste Pensa

This leaflet was last revised in