

Package leaflet: Information for the user

Montelukast Pensa 10 mg film-coated tablets
Montelukast

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you 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 Pensa is and what it is used for
2. What you need to know before you take 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, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

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

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

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

Do not take Montelukast Pensa

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

Warnings and precautions

Tell your doctor or pharmacist before taking Montelukast Pensa

- If your asthma or breathing gets worse, tell your doctor immediately.
- Montelukast Pensa 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 Pensa should not be used instead of other asthma medications your doctor has prescribed.
- 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 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

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 doctor or pharmacist if you are 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 your doctor if you are 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 may be taken with or without food.

Pregnancy, breast feeding and fertility

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

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 lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Montelukast Pensa

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

Use in adults 15 years of age and older:

One Montelukast Pensa 10 mg film-coated tablet daily to be taken in the evening. Montelukast Pensa 10 mg film-coated tablets may be taken with or without food.

If you are taking <Product name>, be sure that you do 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.

If you take more Montelukast Pensa 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 Pensa

Try to take Montelukast Pensa 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 dose.

If you stop taking Montelukast Pensa

Montelukast Pensa can treat your asthma only if you continue to take it. It is important to continue taking Montelukast Pensa for as long as your doctor prescribes. It will help control your 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 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 you get one or more of these symptoms.

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. 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 10 mg montelukast (as sodium salt).

The other ingredients are:

Core: Cellulose microcrystalline, lactose monohydrate, sodium croscarmellose, magnesium stearate (E- 572)

Coating: Polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide (E-171), macrogol/PEG3350, iron oxide yellow (E- 172), iron oxide red (E-172).

What Montelukast Pensa looks like and contents of the pack

The 10 mg film-coated tablets are peach color and biconvex with the code M10 engraved on one side.

The film-coated tablets are provided in blister packs containing 14, 28 and 98 film-coated 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
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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