

Package leaflet: Information for the user

Cinjalair 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, 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

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2. What you need to know before you take Cinjalair
3. How to take Cinjalair
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1. What Cinjalair is and what it is used for

What Cinjalair is

Cinjalair is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Cinjalair works

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Cinjalair improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When Cinjalair should be used

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

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

Your doctor will determine how Cinjalair 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 airways.

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

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. What you need to know before you take Cinfalair

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

Do not take Cinfalair

- if you are 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 taking Cinfalair.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Cinfalair 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 or your child take all asthma medications prescribed by your doctor. Cinfalair should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a 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 and adolescents

Do not give this medicine to children less than 15 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 Cinfalair

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Cinfalair works, or Cinfalair may affect how other medicines

work. Tell your doctor if you are taking the following medicines before starting Cinfalair:

- 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 lipid levels in plasma)

Cinfalair with food and drink

Cinfalair 10 mg film-coated tablet may be taken with or without 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 Cinfalair.

Pregnancy

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

Breast-feeding

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

Driving and using machines

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

Cinfalair 10 mg film-coated tablets contain lactose

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 Cinfalair

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 Cinfalair once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older:

The recommended dose is one 10 mg tablet to be taken daily in the evening.

If you are taking Cinfalair, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

You can take CINFALAIR 10 mg with or without food.

If you take more Cinfalair 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 Cinfalair

Try to take Cinfalair 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 Cinfalair

Cinfalair can treat your asthma only if you continue to take it.

It is important to continue taking Cinfalair 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 10 mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to montelukast were:

- abdominal pain
- 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: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people Uncommon: may affect up to 1 in 100 people Rare: may affect up to 1 in 1,000 people

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

Not known: frequency cannot be estimated from the available data

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*), swelling (inflammation) of the lungs (*Very rare*)
- 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 (See section 2).

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

5. How to store Cinfalair

- Keep out of the reach and sight of children.
- • Do not use this medicine after the date shown by the six numbers following EXP on the blister. The first two numbers indicate the month; the last four numbers indicate the year. This medicine expires at the end of the month shown.
- • Do not store above 30°C.
- • Store in the original package in order to protect from light and moisture.
- • Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cinfalair contains

- The active substance is: montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.
- The other ingredients are: Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Low-substituted Hydroxypropyl-cellulose (E-463), Hydroxypropylcellulose and Magnesium stearate.

Film coating:

Hypromellose, Macrogol 6000, Titanium dioxide (E 171), Talc, Red and yellow iron oxide (E 172).

What Cinfalair looks like and contents of the pack

Cinfalair 10 mg are cream-colored, round, biconvex and engraved with code “M” film-coated tablets.

Cinfalair 10 mg is supplied in packages containing 28 tablets (in 7 tablets blister-packs).

Marketing Authorisation Holder and Manufacturer

LABORATORIOS CINFA, S.A.
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This package leaflet was last revised in September 2015.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**