

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinfalair Paediatrics 4 mg Granules montelukast

Read all of this leaflet carefully before your child starts taking this medicine.

- 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Cinfalair Paediatrics is and what it is used for
2. Before Cinfalair Paediatrics is taken
3. How to take Cinfalair Paediatrics
4. Possible side effects
5. How to store Cinfalair Paediatrics
6. Further information

1. What Cinfalair Paediatrics is and what it is used for

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

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

- Cinfalair Paediatrics is used for the treatment of 6 months to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Cinfalair Paediatrics may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- Cinfalair Paediatrics also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Cinfalair Paediatrics 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. Before Cinalair Paediatrics is taken

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

Do not give Cinalair Paediatrics to your child if he/she

- is allergic (hypersensitive) to montelukast or any of the other ingredients of Cinalair Paediatrics (see 6. Further information).

Take special care with Cinalair Paediatrics

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Cinalair Paediatrics is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child take all asthma medications prescribed by your doctor.

Cinalair Paediatrics should not be used instead of other asthma medications your doctor has prescribed for 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 acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

Taking other medicines

Some medicines may affect how Cinalair Paediatrics works, or Cinalair Paediatrics may affect how your child's other medicines work.

Please tell your doctor or pharmacist if your child is taking or has recently taken other medicines, including those obtained without a prescription.

Tell your doctor if your child is taking the following medicines before starting Cinalair Paediatrics:

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

Taking Cinalair Paediatrics with food and drink

Cinalair Paediatrics granules can be taken without regard to the timing of food intake.

Pregnancy and breast-feeding

This subsection is not applicable for the Cinalair Paediatrics 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Cinalair Paediatrics. Your doctor will assess whether you can take Cinalair Paediatrics during this time.

Use in breast-feeding

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

Driving and using machines

This subsection is not applicable for the Cinfalair Paediatrics 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

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

3. How to take Cinfalair Paediatrics

- This medicine is to be given to a child under adult supervision. Your child should take Cinfalair Paediatrics every evening.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.
- Always have your child take Cinfalair Paediatrics as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth

For children 6 months to 5 years of age:

One sachet of Cinfalair Paediatrics 4 mg granules to be taken by mouth each evening.

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

For children 6 months to 2 years old, Cinfalair Paediatrics 4 mg granules are available. For children 2 to 5 years old, Cinfalair Paediatrics 4 mg chewable tablets and Cinfalair Paediatrics 4 mg granules are available. The Cinfalair Paediatrics 4 mg granules formulation is not recommended below 6 months of age.

How should I give Cinfalair Paediatrics granules to my child?

- Do not open the sachet until ready to use.
- Cinfalair Paediatrics granules can be given either:
 - directly in the mouth;
 - or mixed with a spoonful of cold or room temperature soft food (for example, applesauce, ice cream, carrots and rice).
- Mix all of the contents of the Cinfalair Paediatrics granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.
- Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes). **IMPORTANT:** Never store any granule/food mixture for use at a later time.
- Cinfalair Paediatrics granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the Cinfalair Paediatrics granules.
- Cinfalair Paediatrics granules can be taken without regard to the timing of food intake.

If your child takes more Cinfalair Paediatrics 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 Cinfalair Paediatrics to your child

Try to give Cinfalair Paediatrics as prescribed. However, if your child misses a dose, just resume the usual schedule of one sachet once daily.

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

If your child stops taking Cinfalair Paediatrics

Cinfalair Paediatrics can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Cinfalair Paediatrics 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 product, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, Cinfalair Paediatrics can cause side effects, although not everybody gets them.

In clinical studies with Cinfalair Paediatrics 4 mg granules, 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 Cinfalair Paediatrics were:

- diarrhoea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

Additionally, the following side effects were reported in clinical studies with either Cinfalair Paediatrics 10 mg film-coated tablets, Cinfalair Paediatrics 5 mg or 4 mg chewable tablets:

- abdominal pain
- headache
- thirst

These were usually mild and occurred at a greater frequency in patients treated with Cinfalair Paediatrics 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 your child gets one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5. How to store Cinfalair Paediatrics

- 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 sachet. 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. Further information

What Cinfalair Paediatrics contains

- The active substance is montelukast. Each sachet of granules contains montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredients are: Mannitol, hypromellose (E 463), and magnesium stearate.

What Cinfalair Paediatrics looks like and contents of the pack

Cinfalair Paediatrics 4 mg granules are white to off-white granules granules. Cartons of 28 sachets.

Marketing Authorisation Holder and Manufacturer:

LABORATORIOS CINFA, S.A.

C/ Olaz-Chipi, 10. Polígono Industrial Areta.

31620 Huarte-Pamplona (Navarra) Spain.

This package leaflet was last revised in January 2014

This is medicament

- A medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Strictly follow the doctor's prescription, the method of use, and the instruction of the pharmacist who sold the medicament .
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment period without consulting your physician.
- Do not repeat the same prescription without consulting your doctor.
- Keep medication out of reach & sight of children

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