

Package leaflet: Information for the user

Cinfalair Paediatric 4 mg Granules montelukast

Read all of this leaflet carefully before you give this medicine to your child because it contains important information.

- 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 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's.
- If your child gets 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 Cinfalair Paediatric is and what it is used for
2. What you need to know before your child takes Cinfalair Paediatric
3. How to take Cinfalair Paediatric
4. Possible side effects
5. How to store Cinfalair Paediatric
6. Contents of the pack and other information

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

What Cinfalair Paediatric is

Cinfalair Paediatric is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Cinfalair Paediatric works

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

When Cinfalair Paediatric should be used

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

- Cinfalair Paediatric 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 Paediatric 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 Paediatric also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Cinfalair Paediatric 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 Cinalair Paediatric

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

Do not give Cinalair Paediatric to your child

- if he/she 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 give Cinalair Paediatric to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Cinalair Paediatric 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 Paediatric 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.

Children and adolescents

Do not give this medicine to children less than 6 months 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 Cinalair Paediatric

Tell your doctor or pharmacist if your child is taking or has recently been given or might be given any other medicines including those obtained without a prescription.

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

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

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

Cinalair Paediatric with food and drink

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

Pregnancy and breast-feeding

This subsection is not applicable for the Cinalair Paediatric 4 mg granules since they are

intended for use in children 6 months to 5 years of age.

Driving and using machines

This subsection is not applicable for the Cinfalair Paediatric 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 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.

3. How to take Cinfalair Paediatric

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

- This medicine is to be given to a child under adult supervision. Your child should take Cinfalair Paediatric every evening.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 6 months to 5 years of age:

The recommended dose is one sachet of Cinfalair Paediatric 4 mg granules to be taken by mouth each evening.

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

How should I give Cinfalair Paediatric granules to my child?

This medicine is for oral use.

- Do not open the sachet until ready to use
- Cinfalair Paediatric 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 Paediatric 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 Paediatric granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the Cinfalair Paediatric granules.
- Cinfalair Paediatric granules can be taken without regard to the timing of food intake.

If your child takes more Cinfalair Paediatric 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 Paediatric to your child

Try to give Cinalair Paediatric 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 Cinalair Paediatric

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

It is important for your child to continue taking Cinalair Paediatric 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 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 Cinalair Paediatric 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 Cinalair Paediatric were:

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

Additionally, the following side effects were reported in clinical studies with either Cinalair 10 mg film-coated tablets, Cinalair Paediatric 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 Cinalair 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, sleepwalking, 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 your child gets 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 Paediatric

- 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. Contents of the pack and other information

What Cinfalair Paediatric 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 464), and magnesium stearate.

What Cinfalair Paediatric looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer:

LABORATORIOS CINFA, S.A.
Olaz-Chipi, 10. Polígono Industrial Areta,
31620 Huarte (Navarra) – Spain

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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**