

Package leaflet: Information for the user

Cinfalair 4 mg chewable tablets 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 is and what it is used for
2. What you need to know before your child takes Cinfalair
3. How to take Cinfalair
4. Possible side effects
5. How to store Cinfalair
6. Contents of the pack and other information

1. What Cinfalair is and what it is used for

What Cinfalair is

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

How Cinfalair works

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

When Cinfalair should be used

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

- Cinfalair is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Cinfalair 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 also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Cinfalair 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 Cinfalair

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

Do not give Cinfalair 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 Cinfalair to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral montelukast 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. Cinfalair 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 2 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 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 Cinfalair works, or Cinfalair may affect how your child's other medicines work.

Tell your doctor if your child is 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)

Cinfalair with food and drink

Cinfalair 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

This subsection is not applicable for the Cinfalair 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for the Cinfalair 4 mg chewable tablets since they are intended for

use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

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

Cinjalair 4 mg chewable tablets contain aspartame, a source of phenylalanine

If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each 4 mg chewable tablet contains phenylalanine (equivalent to 0.674 mg phenylalanine per 4 mg chewable tablet).

3. How to take Cinjalair

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. For children who have problems consuming a chewable tablet, an oral granule formulation is available.
- Your child should take only one chewable tablet of Cinjalair once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 2 to 5 years of age:

The recommended dose is one 4 mg chewable tablet daily to be taken in the evening.

If your child is taking Cinjalair, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Cinjalair 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 takes more Cinjalair 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 Cinjalair to your child

Try to give Cinjalair as prescribed. However, if your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

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

If your child stops taking Cinjalair

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

It is important for your child to continue taking Cinjalair 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 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: 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

- Do not store above 30 °C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box/blisters/label after EXP. The expiry date refers to the last day of the 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 Cinfalair contains

- The active substance is montelukast. Each 4 mg Cinfalair tablet contains 4 mg of montelukast (as 4.16 mg of montelukast sodium).
- The other ingredients are: microcrystalline cellulose (E460), mannitol, sodium starch glycollate (potato), aspartame (E951), magnesium stearate (E572), cherry flavour and red iron oxide (E172).

What Cinfalair looks like and contents of the pack

The tablets are reddish, cylindrical, biconvex and engraved with code MO3 on one side.

Cinfalair 4 mg is supplied in packages containing 28 tablets (in 7 tablets blister-packs).

Marketing Authorisation Holder and Manufacturer

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

This package leaflet was last revised in June 2016

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**

Package leaflet: Information for the user

Cinfalair 5 mg chewable tablets montelukast

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

- 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 or 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 or your child's.
- If you or your child 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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1. What Cinfalair is and what it is used for

What Cinfalair is

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

How Cinfalair works

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

When Cinfalair should be used

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

- Cinfalair is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- Cinfalair may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 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 also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Cinfalair should be used depending on the symptoms and severity of your or 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 you take Cinfalair

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

Do not take Cinfalair

- if you or your child 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 or your child take Cinfalair.

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral montelukast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. 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 used instead of other asthma medications your doctor has prescribed for you or your child.
- 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 or 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 asthma worse.

Children and adolescents

Do not give this medicine to children less than 6 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 or your child 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 or your child is 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)

Cinfalair with food and drink

Cinfalair 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after 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 montelukast may affect some patients' ability to drive or operate machinery.

Cinfalair 5 mg chewable tablets contain aspartame, a source of phenylalanine

If you or your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

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 or your child should take only one chewable tablet of Cinfalair once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

For children 6 to 14 years of age:

The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.

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

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Cinfalair 5 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 you or your child takes 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 or give Cinfalair to your child

Try to take Cinfalair as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

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

If you or your child stops taking Cinfalair

Cinfalair can treat you or your child's asthma only if you or your child continues to take it. It is important to continue taking Cinfalair for as long as your doctor prescribes. It will help control you or your child's 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 5 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:

- headache

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

- abdominal pain

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, 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 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 Cinalair

- Do not store above 30 °C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box/blisters/label after EXP. The expiry date refers to the last day of the 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 Cinalair contains

- The active substance is montelukast. Each 5 mg Cinalair tablet contains 5 mg of montelukast (as 5.20 mg of montelukast sodium).
- The other ingredients are: microcrystalline cellulose (E460), mannitol, sodium starch glycollate (potato), aspartame (E951), magnesium stearate (E572), cherry flavour and red iron oxide (E172).

What Cinalair looks like and contents of the pack

The tablets are reddish, cylindrical, biconvex and engraved with code MO2 on one side.

Cinalair 5 mg is supplied in packages containing 28 tablets (in 7 tablets blister-packs).

Marketing Authorisation Holder and Manufacturer

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- 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.

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