

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinfalair 4 mg chewable tablets

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, 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 those of your child.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

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

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

- Cinfalair is used for the treatment of patients between 2 and 5 years of age who are not adequately controlled on their medication and who need additional treatment.
- Cinfalair is also used as an alternative to inhaled corticosteroids in patients between 2 and 5 years of age who have not recently taken oral corticosteroids to treat their asthma and who have shown that they are not able to use inhaled corticosteroids.
- Cinfalair also helps prevent narrowing of the airways caused by exercise in patients aged two years and over.

Depending on the symptoms and severity of your child's asthma, your doctor will determine how Cinfalair should be taken.

What is asthma?

Asthma is a chronic disease. Asthma includes:

- Difficulty breathing due to narrowing of the airways. This narrowing of the 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) of the lining of the airways.

Symptoms of asthma include: coughing, wheezing and a tight chest.

2. What you need to know before you take Cinalair

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

Do not give Cinalair to your child if

- he/she is allergic (hypersensitive) to montelukast or any of the other ingredients of Cinalair (see section 6. Contents of the pack and other information).

Take special care with Cinalair

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Cinalair is not indicated for the treatment of acute asthma attacks. If an attack occurs, follow your doctor's instructions. Always have your child's rescue inhaler medicine with you to treat asthma attacks.
- It is important that your child uses all the asthma medicines prescribed by your doctor. Cinalair should not be substituted for other asthma medicines prescribed by your doctor for your child.
- If your child is being treated with asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, tingling or numbness in the arms or legs, worsening pulmonary symptoms and/or rash, you should see your doctor.
- Your child should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

Other medicines and Cinalair

Some medicines may affect how Cinalair works or Cinalair may affect how other medicines that your child is taking work.

Tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including over-the-counter medicines.

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

- phenobarbital (used for treating epilepsy)
- phenytoin (used for treating epilepsy)
- rifampicin (used for treating tuberculosis and some other infections)

Cinalair with food and drink

Cinalair 4 mg chewable tablets should not be taken with food; it should be taken at least 1 hour before or 2 hours after meals.

Pregnancy and breast-feeding

This subsection is not applicable to Cinalair 4 mg chewable tablets as they are indicated for use in children between 2 and 5 years of age. However, the following information is important for the active substance, montelukast.

Use during pregnancy

Women who are pregnant or planning a pregnancy should consult their doctor before taking Cinalair. Your doctor will assess whether you can take Cinalair during this time.

Use during breast-feeding

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

Driving and using machines

This subsection is not applicable to Cinfalair 4 mg chewable tablets as they are indicated for use in children between 2 and 5 years of age. However, the following information is important for the active substance, montelukast.

Cinfalair is not expected to affect your ability to drive a car or use machines. However, individual responses to the medicine can vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Cinfalair may affect the patient's ability to drive or use machines.

Important information about some of the ingredients of Cinfalair

This medicine may be harmful for people with phenylketonuria since it contains aspartame (E951), which is a source of phenylalanine.

3. How to take Cinfalair

- This medicine must be administered to children under adult supervision. For children who find it hard to take a chewable tablet, an oral granule formulation is available.
- Your child should take only one Cinfalair tablet once a day as prescribed by your doctor.
- It should be taken even if your child has no symptoms or if he/she has an acute asthma attack.
- Always ensure that your child takes Cinfalair exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

For children 2 to 5 years of age:

One 4-mg chewable tablet should be taken daily in the evening. Cinfalair 4 mg chewable tablets should not be taken with food; it should be taken at least 1 hour before or 2 hours after meals.

If your child is taking Cinfalair, make sure he/she does not take any other medicines containing the same active substance, montelukast.

For children 2 to 5 years old, Cinfalair 4 mg chewable tablets and Cinfalair 4 mg granules are available. For children 6 to 14 years old, Cinfalair 5 mg chewable tablets are available. The Cinfalair 4 mg chewable tablet is not recommended in children under the age of 2 years.

If your child takes more Cinfalair than he/she should

Contact your child's doctor immediately for advice. In most cases of overdose, no side effects were reported. The most common symptoms reported with overdose in adults and children were abdominal pain, drowsiness, thirst, headache, vomiting and hyperactivity.

If you forget to give Cinfalair to your child

Try to give Cinfalair as prescribed. However, if you forget to give your child a dose, just resume the usual schedule of one tablet once a day.

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

If your child stops taking Cinfalair

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

It is important for your child to continue taking Cinfalair 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, Cinalair can cause side effects, although not everybody gets them.

In clinical trials with montelukast chewable tablets, the most commonly reported side effects (occurring in at least 1 in 100 patients and in less than 1 in 10 patients treated) related to administration of the medicine were:

- abdominal pain
- thirst

The following side effects were also reported in clinical trials with montelukast 10 mg film-coated tablets and 5 mg chewable tablets:

- headache

These side effects were generally mild and occurred more often in patients treated with montelukast than with placebo (a pill that contains 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).

In addition, since the medicine has been put on the market, the following side effects 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 breathing or swallowing (*uncommon*).
- Behaviour and mood-related changes [dreams 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, seizures (*uncommon*).
- Palpitations (*rare*).
- Nose bleed (*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 in the arms and legs, worsening pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You should immediately inform your doctor if your child has one or more of these symptoms.

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

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 shown by the six numbers after EXP on the blister. The first two numbers indicate the month and the last four numbers indicate the year.

The expiry date refers to the last day of that month.

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 and biconvex-shaped with a code 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.
C/ Olaz-Chipi, 10. Polígono Industrial Areta.
31620 Huarte-Pamplona (Navarra)
Spain.

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.**

This package leaflet was last revised in August 2013

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinjalair 5 mg chewable tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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.

What is in this leaflet:

1. What Cinjalair is and what it is used for
2. What you need to know before you take Cinjalair
3. How to take Cinjalair
4. Possible side effects
5. How to store Cinjalair
6. Contents of the pack and other information

1. What Cinjalair is and what it is used for

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

Your doctor has prescribed Cinjalair to treat asthma and prevent asthma symptoms during the day and night.

- Cinjalair is used for the treatment of patients who are not adequately controlled on their medication and who need additional treatment.
- Cinjalair is also used as an alternative to inhaled corticosteroids in patients between 6 and 14 years of age who have not recently taken oral corticosteroids to treat their asthma and who have shown that they are not able to use inhaled corticosteroids.
- Cinjalair also helps prevent narrowing of the airways caused by exercise.

Depending on the symptoms and severity of your asthma, your doctor will determine how you should take Cinjalair.

What is asthma?

Asthma is a chronic disease. Asthma includes:

- Difficulty breathing due to narrowing of the airways. This narrowing of the 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) of the lining of the airways.

Symptoms of asthma include: coughing, wheezing and a tight chest.

2. What you need to know before you take Cinjalair

Do not take Cinjalair:

- if you are allergic (hypersensitive) to montelukast or any of the other ingredients of Cinfalair (see section 6. Contents of the pack and other information).

Take special care with Cinfalair

- If your asthma or breathing gets worse, tell your doctor immediately.
- Cinfalair is not indicated for the treatment of acute asthma attacks. If an attack occurs, follow your doctor's instructions. Always have your rescue inhaler medicine with you to treat asthma attacks.
- It is important that you use all the asthma medicines prescribed by your doctor. Cinfalair should not be substituted for other asthma medicines prescribed by your doctor.
- Any patient being treated with asthma medicines should be aware that if you develop a combination of symptoms such as flu-like illness, tingling or numbness in the arms or legs, worsening pulmonary symptoms and/or rash, you should see your doctor.
- You should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Use in children

For children 2 to 5 years old, Cinfalair 4 mg chewable tablets and Cinfalair 4 mg granules are available.

For children 6 to 14 years old, Cinfalair 5 mg chewable tablets are available.

Other medicines and Cinfalair

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including over-the-counter medicines.

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

- phenobarbital (used for treating epilepsy)
- phenytoin (used for treating epilepsy)
- rifampicin (used for treating tuberculosis and some other infections)

Cinfalair with food and drink

Cinfalair 5 mg chewable tablets should not be taken with food; it should be taken at least 1 hour before or 2 hours after meals.

Pregnancy and breast-feeding

Use during pregnancy

Ask your doctor or pharmacist for advice before using any medicine.

Women who are pregnant or planning a pregnancy should consult their doctor before taking Cinfalair. Your doctor will assess whether you can take Cinfalair during this time.

Use during breast-feeding

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

Driving and using machines

Cinfalair is not expected to affect your ability to drive a vehicle or use machines. However, individual responses to the medicine can vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Cinfalair may affect the patient's ability to drive or use machines.

Important information about some of the ingredients of Cinfalair

This medicine may be harmful for people with phenylketonuria since it contains aspartame (E951), which is a source of phenylalanine.

3. How to take Cinalair

- Always take Cinalair exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The normal dose is 1 tablet a day.
- It should be taken even if you have no symptoms or if you have an acute asthma attack.
- Always take Cinalair exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

For children 6 to 14 years of age:

One 5-mg chewable tablet should be taken daily in the evening. Cinalair 5 mg chewable tablets should not be taken with food; it should be taken at least 1 hour before or 2 hours after meals.

If you are taking Cinalair, make sure you do not take any other products containing the same active substance, montelukast.

If you take more Cinalair than you should

Contact your doctor immediately for advice.

In most cases of overdose, no side effects were reported. The most common symptoms reported with overdose in adults and children were abdominal pain, drowsiness, thirst, headache, vomiting and hyperactivity.

If you forget to take Cinalair

Try to take Cinalair as prescribed. However, if you forget a dose, just resume the usual schedule of one tablet once a day.

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

If you stop taking Cinalair

Cinalair can treat your asthma only if you continue to take it. It is important to continue taking Cinalair 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, Cinalair can cause side effects, although not everybody gets them.

In clinical trials with montelukast chewable tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) related to administration of the medicine were:

- headache

The following side effects were also reported in clinical trials with montelukast 10 mg film-coated tablets:

- abdominal pain

These side effects were generally mild and occurred more often in patients treated with montelukast than with placebo (a pill that contains 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.

In addition, since the medicine has been on the market, the following side effects 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, seizures (*uncommon*).
- Palpitations (*rare*).
- Nose bleed (*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 reaction (erythema multiforme) that may occur without warning (*very rare*).
- Joint or muscle pain, muscle cramps (*uncommon*).
- Weakness/tiredness, feeling unwell, swelling (*uncommon*); fever (*common*).

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness in the arms and legs, worsening pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You should immediately inform your doctor if you have one or more of these symptoms.

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

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 shown by the six numbers after EXP on the blister. The first two numbers indicate the month and the last four numbers indicate the year. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Cinfalair contains

- The active substance is montelukast. Each 5 mg Cinfalair 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 Cinfalair looks like and contents of the pack

The tablets are reddish, cylindrical and biconvex-shaped with a code on one side.
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