

# Cinfa 4 mg chewable tablets

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

## 1. WHAT CINFA 4 MG IS AND WHAT IT IS USED FOR

Cinfa 4 mg 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, Cinfa 4 mg improves the symptoms of asthma and helps control the disease.

Your doctor has prescribed Cinfa 4 mg to treat your child's asthma and prevent asthma symptoms during the day and night.

- Cinfa 4 mg 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.
- Cinfa 4 mg 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.
- Cinfa 4 mg 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 Cinfa 4 mg 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 CINFA 4 MG

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

### Do not give Cinfa 4 mg to your child if

- he/she is allergic (hypersensitive) to montelukast or any of the other ingredients of Cinfa 4 mg (see section 6. CONTENTS OF THE PACK AND OTHER INFORMATION).

### Take special care with Cinfa 4 mg

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Cinfa 4 mg 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. Cinfa 4 mg 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 Cinfa 4 mg

Some medicines may affect how Cinfa 4 mg works or Cinfa 4 mg 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 Cinfa 4 mg:

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

### Cinfa 4 mg with food and drink

Cinfa 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 Cinfa 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 Cinfa 4 mg. Your doctor will assess whether you can take Cinfa 4 mg during this time.

#### Use during breast-feeding

It is not known if Cinfa 4 mg is excreted in human milk. You should consult your doctor before taking Cinfa 4 mg if you are breast-feeding or are planning to breast-feed.

### Driving and using machines

This subsection is not applicable to Cinfa 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.

Cinfa 4 mg 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 Cinfa 4 mg may affect the patient's ability to drive or use machines.

### Important information about some of the ingredients of Cinfa 4 mg

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

## 3. HOW TO TAKE CINFA 4 MG

- This medicine must be administered to children under adult supervision. Your child should take only one Cinfa 4 mg 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 Cinfa 4 mg 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. Cinfa 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 Cinfa 4 mg, make sure he/she does not take any other medicines containing the same active substance, montelukast.

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

### If your child takes more Cinfa 4 mg 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 Cinfa 4 mg to your child

Try to give Cinfa 4 mg 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 Cinfa 4 mg

Cinfa 4 mg can treat your child's asthma only if he/she continues to take it.

It is important for your child to continue taking Cinfa 4 mg 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, Cinfa 4 mg 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 (*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 CINFA 4 MG

- 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 Cinfa 4 mg contains

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

### What Cinfa 4 mg looks like and contents of the pack

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

Cinfa 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 package leaflet was last revised in August 2013.

### 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.**

**cinfa**

Laboratorios Cinfa, S.A.  
Olaz Chipi 10 P.I.Areta  
31620 Huarte Pamplona  
Navarra. SPAIN

# Cinclair 5 mg chewable tablets

Montelukast

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

**1. WHAT CINCLAIR IS AND WHAT IT IS USED FOR**

Cinclair 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, Cinclair improves the symptoms of asthma and helps control the disease.

- Your doctor has prescribed Cinclair to treat asthma and prevent asthma symptoms during the day and night.
- Cinclair is used for the treatment of patients who are not adequately controlled on their medication and who need additional treatment.
- Cinclair 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.
- Cinclair 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 Cinclair.

**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 CINCLAIR****Do not take Cinclair:**

- if you are allergic (hypersensitive) to montelukast or any of the other ingredients of Cinclair (see section 6. CONTENTS OF THE PACK AND OTHER INFORMATION).

**Take special care with Cinclair**

- If your asthma or breathing gets worse, tell your doctor immediately.
- Cinclair 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. Cinclair 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, Cinclair 4 mg chewable tablets. For children 6 to 14 years old, Cinclair 5 mg chewable tablets are available.

**Other medicines and Cinclair**

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 Cinclair:

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

**Cinclair with food and drink**

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

**Use during breast-feeding**

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

**Driving and using machines**

Cinclair 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 Cinclair may affect the patient's ability to drive or use machines.

**Important information about some of the ingredients of Cinclair**

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

**3. HOW TO TAKE CINCLAIR**

- Always take Cinclair 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 Cinclair 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. Cinclair 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 Cinclair, make sure you do not take any other products containing the same active substance, montelukast.

**If you take more Cinclair 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 Cinclair**

Try to take Cinclair 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 Cinclair**

Cinclair can treat your asthma only if you continue to take it. It is important to continue taking Cinclair 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, Cinclair 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 CINCLAIR**

- 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 Cinclair contains**

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

**What Cinclair looks like and contents of the pack**

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

Cinclair 5 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 - Poligono Industrial Areta  
31620 Huarte-Pamplona (Navarra) - Spain

This package leaflet was last revised in August 2013.

**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.**

**cinfa**

Laboratorios Cinfa, S.A.  
Olaz Chipi 10 P.I. Areta  
31620 Huarte Pamplona  
Navarra. SPAIN

# Cinclair 10 mg film-coated tablets

Montelukast

## 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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Cinclair is and what it is used for.
2. Before you take Cinclair.
3. How to take Cinclair.
4. Possible side effects.
5. How to store Cinclair.
6. Further information.

## 1. WHAT CINCLAIR IS AND WHAT IT IS USED FOR

Cinclair is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, montelukast 10 mg improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

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

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

Your doctor will determine how Cinclair 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 the 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. BEFORE YOU TAKE CINCLAIR

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### Do not take Cinclair if you

- are allergic (hypersensitive) to montelukast or any of the other ingredients of Cinclair (see 6. Further information).

### Take special care with Cinclair

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Cinclair 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. Cinclair 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.

### Use in children

For children 2 to 5 years old, montelukast 4 mg chewable tablets are available.

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

### Taking other medicines

Some medicines may affect how Cinclair works, or Cinclair may affect how other medicines work.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

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

- 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)

### Taking Cinclair with food and drink

Cinclair 10 mg may be taken with or without food.

### Pregnancy and breast-feeding

#### Use in pregnancy

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

#### Use in breast-feeding

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

### Driving and using machines

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

### Important information about some of the ingredients of Cinclair

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 CINCLAIR

- You should take only one tablet of Cinclair once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take Cinclair as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

### For adults 15 years of age and older:

One 10 mg tablet to be taken daily in the evening.

Cinclair 10 mg may be taken with or without food.

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

### If you take more Cinclair 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 Cinclair

Try to take Cinclair 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 Cinclair

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

It is important to continue taking Cinclair for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Cinclair 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 Cinclair were:

- Abdominal pain.
- Headache.

These were usually mild and occurred at a greater frequency in patients treated with Cinclair 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*).
- Nausea (*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 you get 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 doctor or pharmacist.

## 5. HOW TO STORE CINCLAIR

- 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. FURTHER INFORMATION

### What Cinclair 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 Cinclair looks like and contents of the pack

Cinclair 10 mg film-coated tablets are Cream-colored rounded biconvex and engraved film-coated tablets. Cinclair 10 mg is supplied in packages containing 28 tablets (in 7 tablets blister-packs).

### Manufacturer and Marketing Authorisation Holder

Laboratorios Cinfa, S.A.

C/ Olaz-Chipi, 10 - Poligono Industrial Areta  
31620 Huarte-Pamplona (Navarra) - Spain

This package leaflet was last revised in August 2013.

### 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.

**cinfa**

Laboratorios Cinfa, S.A.  
Olaz Chipi 10 P.I.Areta  
31620 Huarte Pamplona  
Navarra. SPAIN