

# MONTELAIR

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking MONTELAIR, speak to your doctor or pharmacist.

### 1. Why am I taking MONTELAIR?

MONTELAIR contains the active ingredient montelukast sodium. MONTELAIR is taken to prevent asthma symptoms, including those that occur during the day and at night time. It also prevents the narrowing of airways triggered by exercise. If you have seasonal allergic rhinitis (hay fever), MONTELAIR also treats your allergic rhinitis symptoms.

For more information, see Section [1. Why am I taking MONTELAIR?](#) in the full CMI.

### 2. What should I know before I take MONTELAIR?

Do not take if you have ever had an allergic reaction to MONTELAIR or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions or take any other medicines. You are pregnant or plan to become pregnant. You are breastfeeding or plan to breastfeed.**

**Your child has a condition called phenylketonuria. The 5 mg and 4 mg chewable tablets contain aspartame, corresponding to 1.5 mg phenylalanine in each 5 mg chewable tablet and 1.2 mg in each 4 mg chewable tablet.**

For more information, see Section [2. What should I know before I take MONTELAIR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MONTELAIR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take MONTELAIR?

- Swallow 10 mg film-coated tablet with a glass of water. Chew 4 mg and 5 mg chewable tablets thoroughly and swallow.

More instructions can be found in Section [4. How do I take MONTELAIR?](#) in the full CMI.

### 5. What should I know while taking MONTELAIR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are taking MONTELAIR.</li><li>Continue taking MONTELAIR every day as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.</li><li>If your asthma gets worse while taking MONTELAIR, tell your doctor immediately.</li><li>If an acute attack of asthma occurs, follow your doctor's instructions on what reliever medicine to use to relieve the attack.</li><li>If you or your child experience behaviour and mood-related changes while taking MONTELAIR, tell your doctor immediately.</li><li>If you become pregnant while taking MONTELAIR, tell your doctor immediately.</li><li>Do not take different MONTELAIR strength tablets to make up the strength you have been prescribed by your doctor. The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not take MONTELAIR to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.</li><li>Do not give MONTELAIR to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>MONTELAIR may cause drowsiness or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Be careful when drinking alcohol while you are taking MONTELAIR. If you drink alcohol, drowsiness or dizziness may be worse.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep MONTELAIR in a cool dry place, away from light, where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while taking MONTELAIR?](#) in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with MONTELAIR. It is important to be aware of them so that you can identify any symptoms if they occur. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MONTELAIR

Active ingredient: *montelukast sodium*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking MONTELAIR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking MONTELAIR.**

**Where to find information in this leaflet:**

- [1. Why am I taking MONTELAIR?](#)
- [2. What should I know before I take MONTELAIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take MONTELAIR?](#)
- [5. What should I know while taking MONTELAIR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking MONTELAIR?

**MONTELAIR contains the active ingredient montelukast sodium.**

MONTELAIR belongs to a group of medicines called leukotriene receptor antagonists. It works by blocking substances in your lungs called leukotrienes that cause narrowing and swelling of airways. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks.

Leukotrienes also cause allergic rhinitis symptoms. By blocking leukotrienes, MONTELAIR improves seasonal allergic rhinitis symptoms.

MONTELAIR is used to treat:

- Asthma, including preventing asthma symptoms during the day and at night. It also prevents the narrowing of airways triggered by exercise.
- Seasonal allergic rhinitis (hay fever), MONTELAIR also treats your allergic rhinitis symptoms.

It can be used in children 2 years of age and older (studies have shown that MONTELAIR does not affect the growth rate of children), teenagers and adults.

MONTELAIR is not used to treat an acute attack of asthma. If an acute attack occurs, follow your doctor's instructions for your reliever medicine, and keep taking your MONTELAIR each night or as prescribed.

As a preventive medicine for asthma, MONTELAIR can be taken alone or in combination with other preventive medicines, such as inhaled corticosteroids. Your doctor may reduce your dose of inhaled corticosteroid while you are taking MONTELAIR.

Asthma is a lung disease and has the following characteristics:

- Narrowed airways causing breathing to become difficult.
- Inflamed airways, which means the lining of airways become swollen.
- Sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

Symptoms of asthma include coughing, wheezing and chest tightness. Not all people with asthma wheeze. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

For further information about asthma, contact the Asthma Foundation in your state on 1800 278 462 or visit [www.asthma.org.au](http://www.asthma.org.au).

Seasonal allergic rhinitis (hay fever) is an allergic response often caused by airborne pollens from trees, grasses, and weeds. The day time and night time symptoms of seasonal allergic rhinitis typically may include stuffy, runny, itchy nose, sneezing, watery, swollen, red, itchy eyes.

Your doctor may have prescribed MONTELAIR for another reason. Ask your doctor if you have any questions about why MONTELAIR has been prescribed for you.

MONTELAIR is not addictive.

## 2. What should I know before I take MONTELAIR?

### Warnings

**Do not give MONTELAIR to children under 2 years of age.**

Safety and effectiveness in children younger than 2 years of age have not been studied.

**Do not take MONTELAIR if:**

- You are allergic to montelukast sodium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take MONTELAIR.
- The expiry date on the pack has passed. If you take MONTELAIR after the expiry date it may not work.
- The packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking MONTELAIR, talk to your doctor.

**Check with your doctor if you:**

- You are pregnant or plan to become pregnant. MONTELAIR has not been studied in pregnant women.
- You are breastfeeding or plan to breastfeed. It is not known if MONTELAIR passes into breast milk.
- You have any other medical conditions.
- Your child has a condition called phenylketonuria. The 5 mg and 4 mg chewable tablets contain aspartame,

corresponding to 1.5 mg phenylalanine in each 5 mg chewable tablet and 1.2 mg in each 4 mg chewable tablet.

- You have any other allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take MONTELAIR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with MONTELAIR and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MONTELAIR.**

### 4. How do I take MONTELAIR?

#### How much to take

- For patients with asthma and/or seasonal allergic rhinitis (hay fever), take MONTELAIR only when prescribed by your doctor.
- For adults and teenagers 15 years and older, the dose is one 10 mg film-coated tablet taken each day.
- For children 6 to 14 years old, the dose is one 5 mg chewable tablet taken each day.
- For children 2 to 5 years old, the dose is one 4 mg chewable tablet taken each day.
- For patients with asthma, take MONTELAIR once a day in the evening.
- For patients with seasonal allergic rhinitis (hay fever), take MONTELAIR once a day as prescribed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions in the box, ask your doctor or pharmacist for help.

#### How to take it

MONTELAIR comes as three types of tablets:

- 10 mg film-coated tablets for adults and teenagers 15 years and older.
- 5 mg chewable tablets for children 6 to 14 years old.
- 4 mg chewable tablets for children 2 to 5 years old.

Swallow the 10 mg film-coated tablet with a glass of water.

Chew the 5 mg or 4 mg chewable tablets thoroughly and swallow. Do not swallow whole.

#### When to take it

##### Asthma

Taking MONTELAIR at bedtime each day, this is expected to have the best effect. It will also help you remember when to take the tablets.

##### Seasonal Allergic Rhinitis (Hay Fever)

Take MONTELAIR once a day as prescribed by your doctor.

Your doctor will advise you on the best time of the day to take your tablet.

##### Asthma and Seasonal Allergic Rhinitis (Hay Fever)

Take MONTELAIR at bedtime each day if you have both asthma and seasonal allergic rhinitis (hay fever).

It does not matter if you take MONTELAIR before or after food.

#### How long to take it

Continue taking MONTELAIR for as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking MONTELAIR.

#### If you forget to take MONTELAIR

Skip the dose you missed and take your next dose as usual. Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

#### If you take too much MONTELAIR

If you think that you have taken too much MONTELAIR, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

##### You should do this even if there are no signs of discomfort or poisoning.

The most common symptoms reported with overdose in adults and children include thirst, sleepiness, dilated pupils, hyperactivity, and stomach pain.

### 5. What should I know while taking MONTELAIR

#### Things you should do

- Continue taking MONTELAIR every day as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.

- If your asthma gets worse while taking MONTELAIR, tell your doctor immediately.
- If an acute attack of asthma occurs, follow your doctor's instructions on what reliever medicine to use to relieve the attack.
- If you or your child experience behaviour and mood-related changes while taking MONTELAIR, tell your doctor immediately.
- If you become pregnant while taking MONTELAIR, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MONTELAIR.

### Things you should not do

- If you have been prescribed the 10 mg film-coated tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg chewable tablets, do not take half a 10 mg film-coated tablet in its place. The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.
- Do not take MONTELAIR to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.
- Do not give MONTELAIR to anyone else, even if they have the same condition as you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how MONTELAIR affects you.**

MONTELAIR may cause drowsiness or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you drink alcohol, drowsiness or dizziness may be worse.

### Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep MONTELAIR in a cool dry place, away from light, where the temperature stays below 25°C.
- Follow the instructions in the box on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to take MONTELAIR or it is out of date, take it to any pharmacy for safe disposal.

Do not take MONTELAIR after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Fluid retention.</li> <li>• Nose bleed.</li> <li>• Headache.</li> <li>• Dizziness.</li> <li>• Drowsiness.</li> <li>• Feeling unusually weak or tired.</li> <li>• Upper respiratory tract infection.</li> <li>• Bedwetting in children.</li> <li>• Muscle aches or cramps, joint pain.</li> <li>• Decreased feeling or sensitivity, especially in the skin.</li> <li>• Pins and needles.</li> <li>• Stomach pain.</li> <li>• Nausea, vomiting.</li> <li>• Diarrhoea.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Behaviour and mood-related changes have been reported in patients taking MONTELAIR:</b></p> <ul style="list-style-type: none"> <li>• Agitation, including aggressive behaviour and/or hostility (such as temper tantrums in children).</li> <li>• Suicidal thoughts and actions.</li> <li>• Tremors.</li> <li>• Irritability, restlessness.</li> <li>• Anxiousness, depression (sad mood).</li> <li>• Disorientation (inability to know correct time, place or person).</li> <li>• Disturbance in attention, memory impairment.</li> <li>• Seeing, feeling or hearing things that are not there (also called hallucinations).</li> <li>• Insomnia, dream abnormalities, difficulty sleeping.</li> <li>• Obsessive-compulsive symptoms.</li> <li>• Tics or unusual movements.</li> <li>• Sleep walking.</li> </ul>	<p><b>You should immediately tell your doctor if you or your child start to have any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Suicidal thoughts and actions.</li> <li>• Skin rash or itchiness.</li> <li>• Increased tendency to bleed, bruising.</li> <li>• Fast or irregular heartbeats, also called palpitations.</li> <li>• Symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.</li> </ul> <p><b>If you have the following side effects, you may be having a serious allergic reaction to MONTELAIR. You may need urgent medical attention. These side effects are rare:</b></p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips, mouth, throat or tongue may cause difficulty in breathing or swallowing.</li> <li>• Pinkish, itchy swellings on the skin, also called hives or nettle rash, severe skin reactions that may occur without warning.</li> <li>• Seizure.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

MONTELAIR is only available with a doctor's prescription.

### What MONTELAIR contains

Active ingredient (main ingredient)	Montelukast sodium
Other ingredients (inactive ingredients)	<p><b>10 mg Film-Coated Tablets</b></p> <ul style="list-style-type: none"> <li>• Microcelac 100 (Lactose monohydrate and microcrystalline cellulose).</li> <li>• Hyprollose.</li> <li>• Croscarmellose sodium.</li> <li>• Magnesium stearate.</li> <li>• Hypromellose.</li> <li>• Titanium dioxide.</li> <li>• Macrogol 6000.</li> <li>• Iron oxide red.</li> <li>• Iron oxide yellow.</li> </ul> <p><b>4 mg and 5 mg Chewable Tablets</b></p> <ul style="list-style-type: none"> <li>• Mannitol.</li> <li>• Microcrystalline cellulose.</li> <li>• Croscarmellose sodium.</li> <li>• Aspartame.</li> <li>• Cherry flavour.</li> <li>• Iron oxide red.</li> <li>• Magnesium stearate.</li> </ul>
Potential allergens	<ul style="list-style-type: none"> <li>• Aspartame and mannitol in the 4 mg and 5 mg chewable tablets only.</li> <li>• Lactose monohydrate in 10 mg film-coated tablets only.</li> </ul>

Do not take MONTELAIR if you are allergic to any of these ingredients.

MONTELAIR 10 mg film-coated tablets, MONTELAIR 5 mg and MONTELAIR 4 mg chewable tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

### What MONTELAIR looks like

#### MONTELAIR 4 Chewable Tablets

Pink coloured, mottled, oval, biconvex, uncoated tablet, debossed "M4" on one side and plain on other side.  
AUST R 184837.

#### MONTELAIR 5 Chewable Tablets

Pink coloured, mottled, round, biconvex, uncoated tablet, debossed "M5" on one side and plain on other side.  
AUST R 184825.

**MONTELAIR 10 Film-Coated Tablets**

Beige coloured, rounded square, biconvex, film-coated tablet debossed "M10" on one side and plain on other side.

AUST R 184828.

**Who distributes MONTELAIR**

Arrotex Pharmaceuticals Pty Ltd

15 - 17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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