

MONTELUKAST INTAS

Consumer Medicine Information (CMI) summary

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

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

1. Why am I taking MONTELUKAST INTAS?

MONTELUKAST INTAS contains the active ingredient montelukast sodium. MONTELUKAST INTAS 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), MONTELUKAST INTAS also treats your allergic rhinitis symptoms.

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

2. What should I know before I take MONTELUKAST INTAS?

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

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

Your child has a condition called phenylketonuria. The 5 mg and 4 mg chewable tablets contain aspartame, corresponding to 0.842 mg phenylalanine in each 5 mg chewable tablet and 0.674 mg in each 4 mg chewable tablet.

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

3. What if I am taking other medicines?

Some medicines may interfere with MONTELUKAST INTAS 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 MONTELUKAST INTAS?

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

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

5. What should I know while taking MONTELUKAST INTAS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking MONTELUKAST INTAS.• Continue taking MONTELUKAST INTAS 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 MONTELUKAST INTAS, 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 experience behaviour and mood-related changes while taking MONTELUKAST INTAS, tell your doctor immediately.• If you become pregnant while taking MONTELUKAST INTAS, tell your doctor immediately.• If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MONTELUKAST INTAS.
Things you should not do	<ul style="list-style-type: none">• If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg tablets, do not take half a 10 mg tablet in its place.• Do not take MONTELUKAST INTAS 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 MONTELUKAST INTAS to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• MONTELUKAST INTAS 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	<ul style="list-style-type: none">• Be careful when drinking alcohol while you are taking MONTELUKAST INTAS. If you drink alcohol,

alcohol	drowsiness or dizziness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Keep MONTELUKAST INTAS in a cool dry place, away from light, where the temperature stays below 25°C.

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

6. Are there any side effects?

Montelukast helps most people with asthma and/or seasonal allergic rhinitis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

MONTELUKAST INTAS

Active ingredient(s): *montelukast sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MONTELUKAST INTAS. **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 MONTELUKAST INTAS.**

Where to find information in this leaflet:

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

1. Why am I taking MONTELUKAST INTAS?

MONTELUKAST INTAS contains the active ingredient Montelukast sodium.

MONTELUKAST INTAS Montelukast 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, montelukast improves seasonal allergic rhinitis symptoms.

MONTELUKAST INTAS is used to treat

- Asthma symptoms, including those that occur during the day and at night-time. It also prevents the narrowing of airways triggered by exercise.
- Seasonal allergic rhinitis (hay fever), MONTELUKAST INTAS also treats your allergic rhinitis symptoms.

It can be used in children 2 years of age and older, teenagers and adults.

MONTELUKAST INTAS 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 MONTELUKAST INTAS each night or as prescribed.

As a preventive medicine for asthma, MONTELUKAST INTAS can be used 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 MONTELUKAST INTAS.

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 645 130, or www.asthmaaustralia.org.au.

Seasonal allergic rhinitis (also known as 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 MONTELUKAST INTAS for another reason. Ask your doctor if you have any questions about why MONTELUKAST INTAS has been prescribed for you.

Montelukast is not addictive

2. What should I know before I take MONTELUKAST INTAS?

Warnings

Do not take MONTELUKAST INTAS 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 MONTELUKAST INTAS.
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.
- the packaging is torn or shows signs of tampering

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

Check with your doctor if you:

- you are pregnant or intend to become pregnant. Montelukast has not been studied in pregnant women.
- you are breast-feeding or plan to breast-feed. It is not known if montelukast 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 MONTELUKAST INTAS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for 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 affect how MONTELUKAST INTAS works, or MONTELUKAST INTAS may affect how your other medicines work.

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

4. How do I take MONTELUKAST INTAS?

How much to take / take

- For patients with asthma and/or seasonal allergic rhinitis, take MONTELUKAST INTAS only when prescribed by your doctor.
- For adults and teenagers 15 years and older, the dose is one 10 mg 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.
- MONTELUKAST INTAS helps control your asthma. Therefore MONTELUKAST INTAS must be taken every day. Continue taking MONTELUKAST INTAS for as long as your doctor prescribes.

When to take MONTELUKAST INTAS

- For patients with asthma, take MONTELUKAST INTAS once a day in the evening.
Take your MONTELUKAST INTAS at bedtime each day if you have both asthma and seasonal allergic rhinitis.
- For patients with seasonal allergic rhinitis, take MONTELUKAST INTAS once a day as prescribed by your doctor.
- For patients with both asthma and seasonal allergic rhinitis, take your MONTELUKAST INTAS at bedtime each day.
- It does not matter if you take MONTELUKAST INTAS before or after food.

How to take MONTELUKAST INTAS

MONTELUKAST INTAS comes as three types of tablets:

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

If you forget to take MONTELUKAST INTAS

MONTELUKAST INTAS should be taken regularly at the same time each day. If you miss your dose at the usual time, Skip the dose you missed and take your next dose as usual.

Do not take a double dose to make up for the dose you missed.

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

If you take too much MONTELUKAST INTAS

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

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

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.

5. What should I know while taking MONTELUKAST INTAS?

Things you should do

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

Do not take MONTELUKAST INTAS to relieve an acute asthma attack. If an acute attack of asthma occurs, follow your doctor's instructions on what reliever medicine to use to relieve the attack.

Call your doctor straight away if:

- your asthma gets worse while taking MONTELUKAST INTAS.
- you experience behavior and mood-related changes while taking MONTELUKAST INTAS. (see "Behaviour and mood related changes under side effects"). **All thoughts of suicide must be taken seriously.**
- you experience a combination of allergic symptoms including a flu-like illness, pins and needles or numbness of arms or legs, and/or rash. In asthmatic patients treated with montelukast, very rare cases have been reported. Although it is unknown if montelukast can cause this condition, you must tell your doctor right away if you get one or more of these symptoms.

- you become pregnant while taking MONTELUKAST INTAS.

Remind any doctor, dentist or you visit that you are taking MONTELUKAST INTAS.

Things you should not do

- If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg tablets, do not take half a 10 mg 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 MONTELUKAST INTAS 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 MONTELUKAST INTAS to anyone else, even if they have the same condition as you.

Driving or taking machines

Be careful before you drive or take any machines or tools until you know how MONTELUKAST INTAS affects you.

MONTELUKAST INTAS may cause dizziness in some people

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- Keep this medicine in a cool dry place, away from light, where the temperature stays below 25°C.

Follow the instructions in the carton 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 this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine 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
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<p>Muscle or nerve problems:</p> <ul style="list-style-type: none"> • muscle aches or cramps, joint pain • decreased feeling or sensitivity especially in the skin • pin and needles <p>Stomach or bowel problems:</p> <ul style="list-style-type: none"> • stomach pain • nausea, vomiting • diarrhoea <p>Respiratory problems:</p> <ul style="list-style-type: none"> • nose bleed • upper respiratory tract infection <p>Head and nervous system problems:</p> <ul style="list-style-type: none"> • headache, dizziness, drowsiness <p>General:</p> <ul style="list-style-type: none"> • fluid retention • feeling unusually weak or tired • bedwetting in children 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>Behaviour and mood-related changes:</p> <ul style="list-style-type: none"> • agitation, including aggressive behaviour and/or hostility (such as temper tantrums in children); • tremors; • irritability, restlessness; • anxiousness, depression (sad mood) • disorientation, dream abnormalities, hallucinations seeing, feeling or hearing things that are not there • disturbance in attention, memory impairment • insomnia, irritability • obsessive-compulsive symptoms • sleep-walking. • Uncontrolled muscle movements <p>These are usually mild side effects of MONTELUKAST INTAS</p>	<p>If you or your child experience these changes while taking montelukast, tell you doctor.</p> <p>Behavior and mood-related changes, including suicidal thoughts and actions, have been reported in patients taking montelukast.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • suicidal thoughts and actions • skin rash or itchiness; • increased tendency to bleed, bruising; • fast or irregular heart-beats, also called palpitations; • symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious</p>

unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.	side effects.
<ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing; pinkish, itchy swellings on the skin, also called hives or nettle rash, severe skin reactions that may occur without warning; seizure. 	<p>If any of the following happen, stop taking MONTELUKAST INTAS and tell your doctor immediately or go to accident and emergency at your nearest hospital</p> <p>You may be having a serious allergic reaction to MONTELUKAST INTAS. You may need urgent medical attention.</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. Some of these side effects (for example, increased bleeding tendency, low blood platelet count) can only be detected when your doctor does tests from time to time to check your progress.

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. 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

This medicine is only available with a doctor's prescription.

What MONTELUKAST INTAS contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> 10 mg film-coated tablet contains 10 mg montelukast (as sodium). 5 mg chewable tablet contains 5 mg montelukast (as sodium). 4 mg chewable tablet contains 4 mg montelukast (as sodium).
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Other ingredients (inactive ingredients)	<p>10 mg film-coated tablets:</p> <ul style="list-style-type: none"> microcrystalline cellulose lactose monohydrate hyprolose croscarmellose sodium magnesium stearate hypromellose titanium dioxide macrogol 6000 iron oxide red iron oxide yellow <p>5 mg and 4 mg chewable tablets:</p> <ul style="list-style-type: none"> mannitol microcrystalline cellulose croscarmellose sodium aspartame cherry 501027 AP0551 (PI 107148) iron oxide red magnesium stearate
Potential allergens	<p>The 10 mg film-coated tablets contain lactose.</p> <p>The 5 mg and 4 mg chewable tablets contain aspartame</p>

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

What MONTELUKAST INTAS looks like

MONTELUKAST INTAS comes as three types of tablets:

- 10 mg tablet: Beige coloured, rounded square, biconvex, film-coated tablet debossed with "M10" on one side and plain on the other side. (AUST R 184834).
- 5 mg chewable tablet: Pink coloured, mottled, round, biconvex, uncoated tablet, debossed with "M5" on one side and plain on the other side. (AUST R 184824)
- 4 mg chewable tablet: Pink coloured, mottled, oval, biconvex, uncoated tablet, debossed with "M4" on one side and plain on the other side. (AUST R 184831)

Who distributes MONTELUKAST INTAS

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121
Australia

This leaflet was prepared in December 2025.