

APX-MONTELUKAST

Consumer Medicine Information (CMI) summary

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

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking APX-MONTELUKAST?

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

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

2. What should I know before I take APX-MONTELUKAST?

Do not take if you have ever had an allergic reaction to APX-MONTELUKAST 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 APX-MONTELUKAST?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-MONTELUKAST 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 APX-MONTELUKAST?

- 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 APX-MONTELUKAST?](#) in the full CMI.

5. What should I know while taking APX-MONTELUKAST?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking APX-MONTELUKAST.• Continue taking APX-MONTELUKAST 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 APX-MONTELUKAST, 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 APX-MONTELUKAST, tell your doctor immediately.• If you become pregnant while taking APX-MONTELUKAST, tell your doctor immediately.• Do not take different APX-MONTELUKAST 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.
Things you should not do	<ul style="list-style-type: none">• Do not take APX-MONTELUKAST 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 APX-MONTELUKAST to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• APX-MONTELUKAST 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	<ul style="list-style-type: none">• Be careful when drinking alcohol while you are taking APX-MONTELUKAST. If you drink alcohol, drowsiness or dizziness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Keep APX-MONTELUKAST 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 APX-MONTELUKAST?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with APX-MONTELUKAST. 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.

APX-MONTELUKAST

Active ingredient: *montelukast sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APX-MONTELUKAST. **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 APX-MONTELUKAST.**

Where to find information in this leaflet:

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

1. Why am I taking APX-MONTELUKAST?

APX-MONTELUKAST contains the active ingredient montelukast sodium.

APX-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, APX-MONTELUKAST improves seasonal allergic rhinitis symptoms.

APX-MONTELUKAST 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), APX-MONTELUKAST also treats your allergic rhinitis symptoms.

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

APX-MONTELUKAST 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 APX-MONTELUKAST each night or as prescribed.

As a preventive medicine for asthma, APX-MONTELUKAST 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 APX-MONTELUKAST.

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.

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

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

APX-MONTELUKAST is not addictive.

2. What should I know before I take APX-MONTELUKAST?

Warnings

Do not give APX-MONTELUKAST 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 APX-MONTELUKAST 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 APX-MONTELUKAST.
- The expiry date on the pack has passed. If you take APX-MONTELUKAST 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 APX-MONTELUKAST, talk to your doctor.

Check with your doctor if you:

- You are pregnant or plan to become pregnant. APX-MONTELUKAST has not been studied in pregnant women.
- You are breastfeeding or plan to breastfeed. It is not known if APX-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 APX-MONTELUKAST.

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 APX-MONTELUKAST 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 APX-MONTELUKAST.

4. How do I take APX-MONTELUKAST?

How much to take

- For patients with asthma and/or seasonal allergic rhinitis (hay fever), take APX-MONTELUKAST 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 APX-MONTELUKAST once a day in the evening.
- For patients with seasonal allergic rhinitis (hay fever), take APX-MONTELUKAST 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

APX-MONTELUKAST 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 APX-MONTELUKAST 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 APX-MONTELUKAST 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 APX-MONTELUKAST at bedtime each day if you have both asthma and seasonal allergic rhinitis (hay fever).

It does not matter if you take APX-MONTELUKAST before or after food.

How long to take it

Continue taking APX-MONTELUKAST 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 APX-MONTELUKAST.

If you forget to take APX-MONTELUKAST

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 APX-MONTELUKAST

If you think that you have taken too much APX-MONTELUKAST, 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 APX-MONTELUKAST

Things you should do

- Continue taking APX-MONTELUKAST 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 APX-MONTELUKAST, 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 including suicidal thoughts while taking APX-MONTELUKAST (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.
- If you become pregnant while taking APX-MONTELUKAST, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking APX-MONTELUKAST.

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 APX-MONTELUKAST 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 APX-MONTELUKAST 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 APX-MONTELUKAST affects you.

APX-MONTELUKAST 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 APX-MONTELUKAST 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 APX-MONTELUKAST or it is out of date, take it to any pharmacy for safe disposal.

Do not take APX-MONTELUKAST 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
<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 • pins and needles/numbness <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>	<p>If you or your child experience</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> agitation, including aggressive behaviour or hostility anxiousness, depression (sad mood) disorientation, dream abnormalities, hallucinations (seeing or hearing things that are not there) insomnia, irritability, restlessness, sleep walking stuttering tremors disturbance in attention, memory impairment uncontrolled muscle movements obsessive-compulsive symptoms <p>These are usually mild side effects of APX-MONTELUKAST</p>	<p>these changes while taking montelukast, tell your doctor.</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 swelling (inflammation) of the lungs 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 	<p>Tell your doctor immediately if you notice any of these serious side effects. You may need urgent medical attention.</p>
<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>Stop taking APX-MONTELUKAST, 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. You may be having a serious allergic reaction to APX-MONTELUKAST. You may need</p>

Serious side effects	What to do
	urgent medical attention.

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

APX-MONTELUKAST is only available with a doctor's prescription.

What APX-MONTELUKAST contains

Active ingredient (main ingredient)	Montelukast sodium
Other ingredients (inactive ingredients)	<p>10 mg Film-Coated Tablets</p> <ul style="list-style-type: none"> Mannitol Microcrystalline cellulose Croscarmellose sodium Iron oxide red Iron oxide yellow Cherry flavour Aspartame Magnesium stearate <p>4 mg and 5 mg Chewable Tablets</p> <ul style="list-style-type: none"> Mannitol Microcrystalline cellulose Iron oxide red Croscarmellose sodium Cherry flavour Aspartame Magnesium stearate
Potential allergens	Aspartame and mannitol

Do not take APX-MONTELUKAST if you are allergic to any of these ingredients.

What APX-MONTELUKAST looks like

APX-MONTELUKAST 4 Chewable Tablets

Pink colored, oval biconvex shaped, uncoated, chewable tablets, with a score line on both sides.

AUST R 189217.

APX-MONTELUKAST 5 Chewable Tablets

Pink colored, round shaped, uncoated, chewable tablets, with a score line on both sides.

AUST R 189216.

APX-MONTELUKAST 10 Film-Coated Tablets

Light brown colored, round biconvex shaped, uncoated tablets, with a score line on both sides.

AUST R 189225.

Who distributes APX-MONTELUKAST

Arrotex Pharmaceuticals Pty Ltd

15 - 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in February 2026.