

AURO-MONTELUKAST TABS 4 & 5

Montelukast sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AURO-MONTELUKAST TABS. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AURO-MONTELUKAST TABS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AURO-MONTELUKAST TABS is used for

AURO-MONTELUKAST TABS is used 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), AURO-MONTELUKAST TABS also treats your allergic rhinitis symptoms.

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

AURO-MONTELUKAST TABS tablets are 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 AURO-MONTELUKAST TABS each night or as prescribed.

As a preventive medicine for asthma, AURO-MONTELUKAST TABS 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 AURO-MONTELUKAST TABS.

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 daytime and nighttime symptoms of seasonal allergic rhinitis typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

How AURO-MONTELUKAST TABS works

AURO-MONTELUKAST TABS 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, AURO-MONTELUKAST TABS improves seasonal allergic rhinitis symptoms.

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

AURO-MONTELUKAST TABS is not addictive.

Before you take AURO-MONTELUKAST TABS

When you must not take it

Do not take AURO-MONTELUKAST TABS if:

- **you have an allergy to AURO-MONTELUKAST TABS or any of the ingredients listed at the end of this leaflet**
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work.

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

Do not give AURO-MONTELUKAST TABS to children under 2 years of age.

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

In studies investigating the effect of AURO-MONTELUKAST TABS on the growth rate of children, it was shown that AURO-MONTELUKAST TABS did not affect the growth rate of children when given for up to 56 weeks in one study.

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**
AURO-MONTELUKAST TABS has not been studied in pregnant women.
2. **you are breast-feeding or plan to breast-feed**
It is not known if AURO-MONTELUKAST TABS passes into breast milk.
3. **you have or have had any medical conditions**
4. **your child has a condition called phenylketonuria**
The 5 mg and 4 mg chewable tablets contain aspartame, corresponding to 0.84 mg phenylalanine in each 5 mg tablet and 0.67 mg in each 4 mg tablet.
5. **you have any 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 any AURO-MONTELUKAST TABS.

Taking other medicines

Some medicines may affect how AURO-MONTELUKAST TABS works, or AURO-MONTELUKAST TABS may affect how your other medicines work.

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

How to take AURO-MONTELUKAST TABS

How much to take

For patients with asthma or seasonal allergic rhinitis, take AURO-MONTELUKAST TABS only when prescribed by your doctor.

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 AURO-MONTELUKAST TABS once a day in the evening.

For patients with seasonal allergic rhinitis, take AURO-MONTELUKAST TABS 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 on the box, ask your doctor or pharmacist for help.

How to take it

AURO-MONTELUKAST TABS comes as three types of tablets:

- 5 mg chewable tablets for children 6-14 years old.
- 4 mg chewable tablets for children 2-5 years old.

Chew the 5 mg or 4 mg chewable tablets thoroughly and swallow.

When to take it

Asthma:

Take your AURO-MONTELUKAST TABS at bedtime each day.

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

Seasonal allergic rhinitis:

Take your AURO-MONTELUKAST TABS 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:

Take your AURO-MONTELUKAST TABS at bedtime each day if you have both asthma and seasonal allergic rhinitis.

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

How long to take it

AURO-MONTELUKAST TABS helps control your asthma. Therefore AURO-MONTELUKAST TABS must be taken every day. Continue taking AURO-MONTELUKAST TABS for as long as your doctor prescribes.

If you forget to take it

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 (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much AURO-MONTELUKAST TABS. 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.

While you are using AURO-MONTELUKAST TABS

Things you must do

Continue taking AURO-MONTELUKAST TABS 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 AURO-MONTELUKAST TABS, 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 become pregnant while taking AURO-MONTELUKAST TABS, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking AURO-MONTELUKAST TABS.

Things you must not do

Do not take AURO-MONTELUKAST TABS 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 AURO-MONTELUKAST TABS to anyone else, even if they have the same condition as you.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AURO-MONTELUKAST TABS.

AURO-MONTELUKAST TABS 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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- fluid retention
- nose bleed

- headache, dizziness, drowsiness
- feeling unusually weak or tired
- upper respiratory tract infection

muscle or nerve problems :

- muscle aches or cramps, joint pain
- decreased feeling or sensitivity, especially in the skin
- pins and needles

stomach or bowel problems :

- stomach pain
- nausea, vomiting
- diarrhoea

Tell your doctor if you notice any of the following behaviour and mood-related changes:

- agitation, including aggressive behaviour and/or hostility
- tremor
- irritability, restlessness, feeling anxious
- depression
- disorientation
- seeing, feeling or hearing things that are not there (also called hallucinations)
- dream abnormalities, difficulty sleeping
- sleep walking

These are usually mild side effects of AURO-MONTELUKAST TABS.

Tell your doctor immediately if you notice any of the following:

- 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 unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- suicidal thoughts and actions

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking AURO-MONTELUKAST TABS and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- 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
- seizure

These may be serious side effects. If you have them, you may be having a serious allergic reaction to AURO-MONTELUKAST TABS. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using AURO-MONTELUKAST TABS

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out the blister pack they may not keep well.

Keep AURO-MONTELUKAST TABS in a cool dry place, away from light, where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What AURO-MONTELUKAST TABS looks like

AURO-MONTELUKAST TABS 4 & 5 (4 mg & 5 mg montelukast as sodium) are presented in pack size of 14 & 28 chewable tablets in blister and 30 chewable tablets in bottle pack.

- **AURO-MONTELUKAST TABS 4**
Pink colored, mottled, oval, biconvex, uncoated tablets debossed with 'X' on one side and '52' on other side.
- **AURO-MONTELUKAST TABS 5**
Pink colored, mottled, round, biconvex, uncoated tablets debossed with 'X' on one side and '53' on other side.

Ingredients

Active ingredient

- Montelukast as sodium

Inactive ingredients

- mannitol
- microcrystalline cellulose
- hydroxypropylcellulose
- iron oxide red CI77491
- croscarmellose sodium
- CD95 art cherry FL SD #594 (PI ARTG No.: 108102)
- aspartame
- magnesium stearate

Name and Address of the Sponsor

Aurobindo Pharma Australia Pty Ltd
Unit 3, North Rydelink Business Park
277-283 Lane Cove Road
Macquarie Park
NSW 2113
Australia

Date of Approval

13 December 2012

Date of Most Recent Amendment

24 January 2013