

## T Lukast 4; T Lukast 5; T Lukast 10

Montelukast sodium

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about T Lukast.

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 T Lukast 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 T Lukast is used for

T Lukast 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), T Lukast also treats your allergic rhinitis symptoms. It can be used in children 2 years of age and older, teenagers and adults.

T Lukast 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 T Lukast each night or as prescribed.

As a preventive medicine for asthma, T Lukast 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 T Lukast.

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](http://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 T Lukast works

T Lukast is in a class of medications called leukotriene receptor antagonists (LTRAs). 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, T Lukast improves seasonal allergic rhinitis symptoms.

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

T Lukast is not addictive.

#### Before you take T Lukast

##### When you must not take it

**Do not take T Lukast if:**

- **you have an allergy to T Lukast 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 T Lukast, talk to your doctor.**

**Do not give T Lukast 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 T Lukast on the growth rate of children, it was shown that T Lukast 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  
T Lukast has not been studied in pregnant women.
2. you are breast-feeding or plan to breastfeed  
It is not known if T Lukast passes into breast milk.
3. **you have or have had any medical conditions**
4. **your child has a condition called phenylketonuria**  
The tablets contain aspartame (a source of phenylalanine)
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 T Lukast.**

##### Taking other medicines

Some medicines may affect how T Lukast works, or T Lukast 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 T Lukast

##### How much to take

**For patients with asthma and/or seasonal allergic rhinitis, take T Lukast only when prescribed by your doctor.**

For adults and teenagers 15 years of age and older: one 10 mg tablet.

For paediatric patients 6 to 14 years of age: one 5 mg tablet.

For paediatric patients 2 to 5 years of age: one 4 mg tablet

**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

T Lukast 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.

Swallow the 10 mg tablet with a glass of water.

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

##### When to take it

- **Asthma:**  
**Take your T Lukast 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 T Lukast 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 T Lukast at bedtime each day if you have both asthma and seasonal allergic rhinitis.**

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

##### How long to take it

T Lukast helps control your asthma.

Therefore T Lukast must be taken every day.

Continue taking T Lukast 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 T Lukast. 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.

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## While you are taking T Lukast

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### *Things you must do*

Continue taking T Lukast 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 T Lukast, 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 T Lukast, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking T Lukast.

### *Things you must 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 T Lukast 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 T Lukast to anyone else, even if they have the same condition as you.

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## Side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking T Lukast.

T Lukast 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 T Lukast.

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 T Lukast 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 T Lukast. 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.

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## After taking T Lukast

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### *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 T Lukast in a cool dry place, away from light, where the temperature stays below 30°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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### *What it looks like*

T Lukast comes as three types of tablets:

- 10 mg tablet - Light brown colored, round biconvex shaped, uncoated tablets, with breakline on both the sides.
- 5 mg chewable tablet - pink colored, round shaped, uncoated tablets, with break line on both the sides.

- 4 mg chewable tablet - pink colored, oval biconvex shaped, uncoated tablets, with breakline on both the sides.

Supplied in blister packs of 4 x 7 tablets

### *Ingredients*

#### **Active ingredient:**

- 10 mg tablet contains 10 mg montelukast
- 5 mg chewable tablet contains 5 mg montelukast
- 4 mg chewable tablet contains 4 mg montelukast

#### **Inactive ingredients:**

1. 10 mg tablets: mannitol, microcrystalline cellulose, croscarmellose sodium, iron oxide red, iron oxide yellow, cherry flavour, aspartame and magnesium stearate
2. 5 mg and 4 mg chewable tablets: mannitol, microcrystalline cellulose, iron oxide red, croscarmellose sodium, cherry flavour, aspartame, and magnesium stearate.

### *Supplier*

**Torrent Australasia Pty Ltd**  
Level 9/10 George Street,  
Parramatta NSW 2150  
Australia

It is distributed in Australia by:

**Alphapharm Pty Limited**  
(ABN 93 002 359 739)  
Level 1, 30 The Bond  
30-34 Hickson Road  
Millers Point NSW 2000  
Phone: (02) 9298 3999  
www.alphapharm.com.au

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#### **AUST R Numbers:**

10 mg tablets: AUST R 189238  
5 mg tablets: AUST R 189246  
4 mg tablets: AUST R 189232