

SINGULAIR®

montelukast sodium

4 mg, 5 mg & 10 mg tablets

What is in this leaflet

This leaflet answers some common questions about SINGULAIR. 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 SINGULAIR 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 SINGULAIR is used for

SINGULAIR is used to treat:

- asthma, including preventing asthma symptoms during the day and night. It also prevents the narrowing of airways triggered by exercise.
- seasonal and year-round allergies, including daytime and nighttime symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

SINGULAIR can be used in children 2 years of age and older, teenagers and adults. SINGULAIR tablets are not used to treat an **acute** attack of asthma. If an acute attack occurs, follow your doctor's instructions for that situation.

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.

Seasonal allergies (also known as hay fever) are triggered by outdoor allergens such as airborne pollens from trees, grasses and weeds.

Year-round allergies may occur year-round and are generally triggered by indoor allergens such as dust mites, animal dander, and/or mould spores.

The daytime and nighttime symptoms of allergies typically may include:

- stuffy, runny, itchy nose
- sneezing
- watery, swollen, red, itchy eyes.

SINGULAIR 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 allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and year-round, also known as outdoor and indoor nasal allergies).

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

SINGULAIR is not addictive.

Before you take SINGULAIR

When you must not take it

Do not take SINGULAIR if:

- you have an allergy to SINGULAIR 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 SINGULAIR, talk to your doctor.

Do not give SINGULAIR to children under 2 years of age. Safety and effectiveness in children younger than 2 years of age have not been studied.

Before you start to take it

Tell your doctor if:

- you are pregnant or intend to become pregnant.
SINGULAIR has not been studied in pregnant women.
- you are breast-feeding or plan to breast-feed.
It is not known if SINGULAIR passes into breast milk.
- if you have or have had any medical conditions
- if 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 SINGULAIR.

Taking other medicines

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.

Some medicines may affect the way other medicines work. In general, SINGULAIR does not interfere with other medicines that you may be taking. However, some medicines may affect how SINGULAIR works, or SINGULAIR may affect how your other medicines work.

How to take SINGULAIR

How much to take

Take SINGULAIR only when prescribed by your doctor.

For adults and teenagers 15 years and older, for the treatment of asthma, seasonal and year-round allergies, the dose is one 10 mg tablet taken daily.

For children 6 to 14 years old, for the treatment of asthma, seasonal and year round allergies, the dose is one 5 mg chewable tablet taken daily.

For children 2 to 5 years old, for the treatment of asthma, seasonal and year round allergies, the dose is one 4 mg chewable tablet taken daily.

Studies have shown that SINGULAIR does not affect the growth rate of children.

For patients with asthma, take SINGULAIR once a day in the evening.

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

SINGULAIR 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 4 mg or 5 mg chewable tablet thoroughly and swallow.

When to take it

Take your SINGULAIR at bedtime each day.

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

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

How long to take it

SINGULAIR helps control your asthma. Therefore SINGULAIR must be taken every day. Continue taking SINGULAIR for as long as your doctor prescribes.

If you forget to take it

Skip the dose you missed and take your next dose at bedtime 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 the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, if you think that you or anyone else may have taken too much SINGULAIR. Do this even if there are no signs of discomfort or poisoning.

While you are using SINGULAIR

Things you must do

Continue taking SINGULAIR 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 SINGULAIR, tell your doctor immediately.

If an acute attack of asthma occurs, follow your doctor's instructions on what medicines to use to relieve the attack.

If you experience behaviour and mood-related changes while taking SINGULAIR, tell your doctor immediately.

If you become pregnant while taking SINGULAIR, tell your doctor immediately.

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

Things you must not do

Do not give SINGULAIR to anyone else, even if they have the same condition as you.

Adverse Effects

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

SINGULAIR helps most people with asthma, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse 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:

- headache
- stomach pain
- thirst

In studies, these are the more common adverse effects of SINGULAIR. For the most part these have been mild and occurred as often in patients treated with SINGULAIR or placebo (a tablet containing no medicine).

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency
- behaviour and mood related changes [agitation including aggressive behaviour or hostility, depression, disorientation, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, restlessness, sleep walking, suicidal thoughts and actions, tremor]
- dizziness, drowsiness, pins and needles/numbness
- palpitations
- nose bleed
- diarrhoea, dyspepsia, nausea, vomiting
- hepatitis

- bruising, rash, and itching
- joint pain, muscle aches and muscle cramps
- weakness/tiredness
- swelling
- fever

If any of the following happen, stop taking SINGULAIR and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives (severe and sudden onset of pinkish itchy swellings on the skin, also called nettlerash)], severe skin reactions that may occur without warning
- seizure, fit or convulsions.

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

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using SINGULAIR

Storage

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 SINGULAIR in a cool dry place 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 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 it looks like

SINGULAIR comes as two types of tablets:

- 10 mg tablet - beige, rounded square tablet with SINGULAIR marked on one side and MSD 117 on the other.
- 5 mg chewable tablet - pink, round tablet with SINGULAIR marked on one side and MSD 275 on the other.
- 4 mg chewable tablet - pink, round tablet with SINGULAIR marked on one side and MSD 711 on the other. (Currently not available in New Zealand).

A box of SINGULAIR contains 28 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:

10 mg tablets

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- hydroxypropyl cellulose
- magnesium stearate
- hydroxypropyl methylcellulose
- titanium dioxide
- ferric oxide red
- ferric oxide yellow
- carnauba wax

4 mg and 5 mg chewable tablets

- mannitol
- microcrystalline cellulose
- hydroxypropyl cellulose
- ferric oxide red
- croscarmellose sodium
- cherry flavour
- aspartame
- magnesium stearate

SINGULAIR 10 mg tablets, 5 mg and 4 mg chewable tablets do not contain gluten, sucrose, tartrazine or any other azo dyes. The 10 mg tablets contain lactose; the 4 mg and 5 mg chewable tablets do not.

Supplier

SINGULAIR is supplied in New Zealand by

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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