

SINGULAIR®

Montelukast Sodium (4mg Oral Granules, 4mg Chewable Tablets, 5mg Chewable Tablets, 10mg Film-Coated Tablets)

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What *SINGULAIR* is used for

Your doctor has prescribed *SINGULAIR* (montelukast sodium) to treat:

- Asthma, including preventing your asthma symptoms during the day and night. *SINGULAIR* also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: 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.

What is asthma?

Asthma is a chronic lung disease. It cannot be cured – only controlled.

Characteristics of asthma include:

- Narrowed airways causing breathing to become difficult. This narrowing worsens and improves in response to various conditions.
- Inflamed airways; that is, 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.

What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction (EIB) occurs when exercise triggers symptoms of asthma.

How do I know if I have asthma?

Your doctor will determine if you have asthma based on your symptoms and/or on how well you are able to move air out of your lungs. Your doctor may use a device called a peak flow meter or a spirometer to test your lung function.

Treatment can control asthma. It is important to treat even mild symptoms of asthma so that you can prevent them from getting worse.

How should asthma be treated?

To help prevent asthma symptoms and improve your breathing you will have to work closely with your doctor to:

Plan ways to avoid or reduce contact with conditions that may trigger an asthma episode (for example, smoking including second-hand smoke, house dust mites, cockroaches, molds, pollen, animal dander, changes in weather and temperature, and infections in the upper airway (such as colds)). Develop a treatment plan that best controls your asthma.

Why is compliance (taking my medicine as prescribed) important?

Taking your medicine as your doctor or health care provider instructs may help reduce the severity of your asthma and the frequency of your asthma attacks.

What is allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as airborne pollens from trees, grasses, and weeds.
- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such as dust mites, animal dander, and/or mold spores.
- The daytime and nighttime symptoms of allergic rhinitis typically may include:
 - stuffy, runny, itchy nose
 - sneezing
 - watery, swollen, red, itchy eyes

How *SINGULAIR* works

SINGULAIR is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Before you use *SINGULAIR*

-When you must not take it

Do not take *SINGULAIR* if you or your child

- are allergic to any of its components.

-Before you start to use it

Tell your doctor (or health care provider) about any medical problems or allergies you or your child has now or has had.

Use in children

For children 6 to 14 years old, *SINGULAIR* 5-mg chewable tablets are available.

For children 2 to 5 years old, *SINGULAIR* 4-mg chewable tablets

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and SINGULAIR 4-mg oral granules are available.

For children 12 months to 2 years old, SINGULAIR 4-mg oral granules are available.

Safety and effectiveness of SINGULAIR in children less than 12 months old have not been established.

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

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking SINGULAIR.

Use in breast-feeding

It is not known if SINGULAIR appears in breast milk. You should consult your doctor before taking SINGULAIR if you are breast-feeding or intend to breast-feed.

-Taking other medicines

In general, SINGULAIR does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how SINGULAIR works, or SINGULAIR may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child is using or plan to use, including those obtained without a prescription.

Can I drive or operate machinery while using SINGULAIR?

SINGULAIR is not expected to affect your ability to drive a car or operate machinery.

How to use SINGULAIR

Take SINGULAIR once a day with or without food, as your doctor has prescribed.

- The dose for adults and adolescents 15 years and older for the treatment of

asthma and/or allergic rhinitis is one 10-mg tablet daily.

- The dose for children 6 to 14 years old for the treatment of asthma and/or allergic rhinitis is one 5-mg chewable tablet daily.
- The dose for children 2 to 5 years old for the treatment of asthma and/or allergic rhinitis is one 4-mg chewable tablet daily or one packet of 4-mg oral granules daily.
- The dose for children 12 months to 2 years old for the treatment of asthma or perennial allergic rhinitis is one packet of 4-mg oral granules daily.

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

For patients with allergic rhinitis, take SINGULAIR once a day as prescribed by your doctor.

It is important to continue taking SINGULAIR for as long as your doctor prescribes it in order to maintain control of your or your child's asthma. SINGULAIR can treat your or your child's asthma only if you or your child continues to take it.

How should I give SINGULAIR oral granules to my child?

Do not open the packet until ready to use.

SINGULAIR oral granules can be given:

- directly in the mouth;
- dissolved in 1 teaspoonful (5 mL) of cold or room temperature baby formula or breast milk;
- mixed with a spoonful of cold or room temperature soft food (for example, applesauce).
- Mix all of the contents of the SINGULAIR oral granules into a spoonful of cold or room temperature soft food, or 1 teaspoonful of cold or room temperature baby formula or breast milk, taking care to see that the

entire dose is mixed with the food, baby formula, or breast milk.

- Be sure the child is given the entire spoonful of the oral granules mixed with food, baby formula, or breast milk immediately (within 15 minutes). IMPORTANT: Never store any oral granules mixed with food, baby formula, or breast milk for use at a later time.

SINGULAIR oral granules are not intended to be dissolved in any liquid other than baby formula or breast milk. However, your child may take liquids after swallowing the SINGULAIR oral granules.

-If you forget to use it

Try to take SINGULAIR as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet or packet once daily.

-If you use too much (overdose)

Contact your doctor immediately.

While you are using SINGULAIR

-Things you must do

It is important that you or your child continue taking SINGULAIR daily as prescribed by your doctor, even when you or your child has no symptoms or if you or your child has an asthma attack.

If your or your child's asthma symptoms get worse, you should contact your doctor immediately.

SINGULAIR is not for the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.

Behavior and mood-related changes have been reported in patients taking SINGULAIR. If you or your child experience these changes while taking

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SINGULAIR (see "Side effects"), tell your doctor.

-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 chewable 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 *SINGULAIR* to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.

Remember that your doctor has prescribed this medicine only for you or your child. Never give it to anyone else.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. *SINGULAIR* is generally well-tolerated. In studies, the most common side effects reported were abdominal pain, headache, thirst, diarrhea, hyperactivity, asthma, scaly and itchy skin, and rash. These were usually mild and occurred as often in patients treated with *SINGULAIR* or placebo (a pill containing no medication).

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency, low blood platelet count
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression,

disorientation, disturbance in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal thoughts and actions, tremor, uncontrolled muscle movements]

- dizziness, drowsiness, pins and needles/numbness, very rarely seizure
- palpitations
- nose bleed; swelling (inflammation) of the lungs
- diarrhea, dyspepsia, nausea, vomiting
- hepatitis
- bruising, severe skin reactions (erythema multiforme) that may occur without warning
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- weakness/tiredness
- swelling
- fever

Tell your doctor or pharmacist if you or your child develops any unusual symptom, or if any known symptom continues or worsens.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about *SINGULAIR* and the condition for which it was prescribed?

You may obtain further information from your physician or pharmacist, who have more detailed information about *SINGULAIR* and your condition.

Storage and Disposal of *SINGULAIR*

-Storage

Store the 10-mg film-coated tablets, 5-mg chewable tablets, 4-mg chewable tablets and the packets of 4-mg oral granules below 30°C (86°F), protected from moisture and light. Store in original package.

How long should I keep my medicine?

Do not use this medicine after the date shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

SINGULAIR 4MG CHEWABLE TABLET:

A pink, oval, biconvex tablet plain on one side and 711 on the other.

SINGULAIR 5MG CHEWABLE TABLET:

A pink, round, biconvex tablet plain on one side and 275 on the other.

SINGULAIR 10MG TABLET:

A beige, rounded square film-coated tablet plain on one side and 117 on the other.

SINGULAIR 4MG ORAL GRANULES:

White, granular, coarse, free-flowing homogeneous solid, with no extraneous particles present.

-Ingredients

SINGULAIR®

Montelukast Sodium (4mg Oral Granules, 4mg Chewable Tablets, 5mg Chewable Tablets, 10mg Film-Coated Tablets)

SINGULAIR (montelukast sodium) contains montelukast sodium as the active ingredient.

Each 10-mg tablet contains 10 mg montelukast, each 5-mg chewable tablet contains 5 mg montelukast, each 4-mg chewable tablet contains 4 mg montelukast and each packet of 4-mg oral granules contains 4 mg montelukast.

In addition, *SINGULAIR* contains the following inactive ingredients:

SINGULAIR 4mg and 5mg Chewable Tablet: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, red ferric oxide; croscarmellose sodium, cherry flavor, aspartame, purified water, magnesium stearate.

SINGULAIR Tablet 10mg: microcrystalline cellulose, hydroxypropyl cellulose, Lactose Monohydrate, croscarmellose sodium, purified water, magnesium stearate, methylhydroxypropylcellulose, titanium dioxide, red ferric oxide, yellow ferric oxide, carnauba wax

SINGULAIR 4mg Oral Granules: mannitol, hydroxypropyl cellulose, purified water, magnesium stearate.

-MAL number:

SINGULAIR 4MG CHEWABLE

TABLET: MAL20020121ARZ

SINGULAIR CHEWABLE TABLET

5MG: MAL19990956ARZ

SINGULAIR TABLET 10MG:

MAL19990957ARZ

SINGULAIR 4MG ORAL

GRANULES: MAL14075049ACRZ

Manufacturer

SINGULAIR 4, 5 & 10mg Tablet
Organon Pharma (UK) Limited
Shotton Lane
Cramlington, Northumberland
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SINGULAIR 4mg Oral Granules

PATHEON MANUFACTURING
SERVICES LLC

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Product Registration Holder

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