

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986

This medicine can be sold under doctor's prescription only

SINGULAIR® 4 mg
GRANULES FOR KIDDIES

Each sachet of granules contains:
Montelukast (as sodium) 4 mg

SINGULAIR® 4 mg
CHEWABLE TABLETS FOR
PRE-SCHOOL KIDS

Each chewable tablet contains:
Montelukast (as sodium) 4 mg

SINGULAIR® 5 mg
CHEWABLE TABLETS

Each chewable tablet contains:
Montelukast (as sodium) 5 mg

SINGULAIR® 10 mg
TABLETS

Each tablet contains:
Montelukast (as sodium) 10 mg

For a list of inactive ingredients see section 6 "FURTHER INFORMATION". See also section 2.6 "Important information about some of the ingredients of **SINGULAIR**"

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **SINGULAIR**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

What is the most important information I should know about SINGULAIR?

- **Serious mental health problems have happened in people taking SINGULAIR** or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking **SINGULAIR** and tell your healthcare provider right away if you or your child have any unusual changes in behavior or thinking, including any of these symptoms:
agitation, including aggressive behavior or hostility, attention problems, bad or vivid dreams, depression, disorientation (confusion), feeling anxious, irritability, hallucinations (seeing or hearing things that are not really there), memory problems, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal thoughts and actions (including suicide), tremor, trouble sleeping, uncontrolled muscle movements.

1. WHAT SINGULAIR IS INTENDED FOR?

SINGULAIR is indicated for the prophylaxis and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, the treatment of aspirin-sensitive asthmatic patients, and the prevention of exercise-induced bronchoconstriction in adult and pediatric patients 12 months of age and older.

SINGULAIR is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and in pediatric patients 2 years of age and older. The use of **SINGULAIR** for seasonal allergic rhinitis is reserved for patients who have an intolerance to alternative therapies since the benefits of **SINGULAIR** may not outweigh the risk of Serious mental health problems [see "What is the most important information I should know about **SINGULAIR**"].

THERAPEUTIC GROUP: SINGULAIR is a selective antagonist of the leukotriene receptor.

SINGULAIR acts by blocking receptors in the airway for substances known as leukotrienes, which cause bronchoconstriction, and swelling of the airways. Leukotrienes also cause allergy symptoms.

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.

What is seasonal allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as 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

2. BEFORE USING SINGULAIR

2.1 Do not use SINGULAIR if:

You are hypersensitive (allergic) to montelukast or any of the other ingredients of SINGULAIR (see sections 6.1 and 2.6).
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2.2 Special Warnings concerning use of SINGULAIR

Before starting treatment with SINGULAIR, tell your doctor:

- If you are allergic to aspirin.
- If you have or have had mental health problems.

Additional warnings:

- If your or your child's asthma symptoms get worse, you should contact your doctor immediately.
- This medicine is not intended for use in acute asthmatic attacks; in such cases, follow the instructions your doctor has given you for such situations. Always have with you the inhaler medicines that the doctor told you to use for acute attack.

Children and adolescents

Safety and effectiveness in pediatric patients younger than 12 months of age with asthma have not been established.

2.3 Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should tell the doctor or pharmacist.

Some medicines may affect how **SINGULAIR** works, or **SINGULAIR** may affect how your other medicines work.

If you have asthma and aspirin makes your asthma symptoms worse, continue to avoid taking aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) while taking **SINGULAIR**.

Especially inform your doctor if you are taking: antiasthmatic preparations such as bronchodilators and steroids for inhalation or for oral use.

2.4 Taking SINGULAIR with food and drink

SINGULAIR may be taken with or without food.

2.5 Pregnancy and Breast-feeding

Before taking **SINGULAIR**, tell your doctor if you:

- are pregnant or plan to become pregnant. Talk to your doctor if you are pregnant or plan to become pregnant, as **SINGULAIR** may not be right for you.
- are breast-feeding or plan to breast-feed. It is not known if **SINGULAIR** passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking **SINGULAIR**.

2.7 Important information about some of the ingredients of SINGULAIR

SINGULAIR 10 mg film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product (see section 6 “FURTHER INFORMATION”).

Before taking **SINGULAIR** 4 mg chewable tablets and **SINGULAIR** 5 mg chewable tablets, tell your doctor if you have phenylketonuria. **SINGULAIR** chewable tablets contain aspartame, a source of phenylalanine (see section 6 “FURTHER INFORMATION”). It may be harmful for children with phenylketonuria. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each **SINGULAIR** 4 mg chewable tablet and each **SINGULAIR** 5 mg chewable tablet contains phenylalanine (equivalent to 0.674 mg and 0.842 mg of phenylalanine per chewable tablet respectively).

3. HOW SHOULD YOU USE SINGULAIR?

Always take **SINGULAIR** as instructed by your doctor. You should check with your doctor or pharmacist if you are not sure about the dosage and method of treatment.

The dosage and method of treatment will be determined by the doctor only.

The usually recommended dose is:

Adults and adolescents 15 years of age and older with Asthma and/or Seasonal Allergic Rhinitis: one 10-mg tablet daily.

Children 6 to 14 years of age with Asthma and/or Seasonal Allergic Rhinitis: one 5-mg chewable tablet daily.

Children 2 to 5 years of age with Asthma and/or Seasonal Allergic Rhinitis: one 4-mg chewable tablet daily or one sachet of 4-mg oral granules daily.

Children 12 months of age to 2 years with Asthma: one sachet of 4-mg oral granules daily.

Do not exceed the recommended dosage.

SINGULAIR should be taken once daily with or without food, according to doctor's instructions.

For asthma, **SINGULAIR** should be taken once daily, in the evening.

For seasonal allergic rhinitis, **SINGULAIR** should be taken once daily according to doctor's instructions.

Always have your inhaled rescue medicine for asthma attacks with you.

Do not take an additional dose of **SINGULAIR** within 24 hours of previous dose.

SINGULAIR chewable tablets are not intended for use in children under 2 years of age.

Directions for use:

SINGULAIR 10 mg tablets

Swallow the tablet, with some water and without regard to meals.

No information is available regarding crushing, chewing or splitting the tablets

SINGULAIR 4 mg and 5 mg chewable tablets

Chew the tablet before swallowing, without regard to meals.

No information is available regarding crushing or splitting the tablets

SINGULAIR 4 mg granules for kiddies

Do not open the sachet until ready to use.

SINGULAIR 4 mg granules for kiddies 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, rice or ice cream).
- Mix all of the contents of the **SINGULAIR 4 mg granules for kiddies** 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 **SINGULAIR 4 mg granules for kiddies** mixed with food, baby formula, or breast milk immediately (within 15 minutes).

IMPORTANT: Never store any **SINGULAIR 4 mg granules for kiddies** mixed with food, baby formula, or breast milk for use at a later time.

SINGULAIR 4 mg granules for kiddies 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 4 mg granules for kiddies**.

If you have accidentally taken a higher dose of SINGULAIR

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take SINGULAIR

If you forget to take this medicine at the specified time, do not take the missed dose as soon as you remember. Simply continue to follow your regular schedule as recommended by the attending doctor. Do not take a double dose to make up for a forgotten dose.

Complete the treatment as recommended by the doctor.

Even if there is an improvement in your or your child's health, or if you or your child has an asthma attack, do not discontinue use of this medicine or change the schedule of its administration without consulting your doctor.

Avoid, as far as possible, contact with factors which can potentially cause an asthmatic attack, such as smoking, mites in dust dander, mold, pollens, animals, changes in weather, exposure to cold air.

If you have asthma and aspirin makes your asthma symptoms worse, continue to avoid taking aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) while taking **SINGULAIR**.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this product, ask the doctor or the pharmacist.

4. SIDE EFFECTS

Like all medicine, **SINGULAIR** can cause side effects in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

SINGULAIR may cause serious side effects, including:

- **Serious mental health problems** (see "What is the most important information I should know about **SINGULAIR**?" at the beginning of this leaflet).
- **Increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis)**. Rarely, this can happen in people with asthma who take **SINGULAIR**. This sometimes happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered.

Consult your doctor right away if you get one or more of these symptoms:

a feeling of pins and needles or numbness of arms or legs, a flu-like illness, rash, severe inflammation (pain and swelling) of the sinuses (sinusitis).

The most common side effects of SINGULAIR include:

- upper respiratory infection
- fever
- headache
- sore throat
- cough
- abdominal pain
- diarrhea
- earache or ear infection
- flu
- runny nose
- sinus infection

Additionally, the following side effects have been reported as well:

- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching].
- dizziness, drowsiness, sleepiness, seizures.
- change in your vision, swelling or redness in or around the eye.
- palpitations (irregular heart beat)
- nose bleed; stuffy nose, swelling (inflammation) of the lungs
- heartburn, diarrhea, stomach pain, dyspepsia, nausea, vomiting, dental pain
- symptoms of liver problems include nausea, vomiting, fatigue, jaundice (yellowing of the skin and eyes), dark urine, flu-like symptoms, loss of appetite, and pain in your abdomen.
- severe skin reactions (Stevens-Johnson syndrome/toxic epidermal necrolysis / erythema multiforme) have been reported, symptoms include blisters, rash, scaly and itchy skin; tender red lumps under the skin, most commonly on your shins (erythema nodosum), bruising.
- Musculoskeletal and connective tissue disorders: joint pain, muscle aches and muscle cramps
- weakness/tiredness, swelling.
- increased bleeding tendency, low blood platelet count, elevated liver enzymes, elevated number of white blood cells in the urine (Pyuria).
- bedwetting in children has been reported.

If a side effect appears, if any of the side effects gets serious or if you suffer from a side effects not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il/>

5. HOW TO STORE SINGULAIR?

Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not use **SINGULAIR** after the expiry date (exp. date) that appears on the packaging. The expiry date refers to the last day of the indicated month.

Storage conditions:

SINGULAIR 4 mg granules for kiddies: Store in the original package in order to protect from light and moisture. Do not store above 25°C. After opening, use within 15 minutes.

SINGULAIR 4 mg chewable tablets: Store in the original package in order to protect from light and moisture, store below 25°C.

SINGULAIR 5 mg chewable tablets: Store in the original package in order to protect from light and moisture. Store below 30°C.

SINGULAIR 10 mg tablets: Store in the original package in order to protect from light and moisture. Store below 30°C.

6. FURTHER INFORMATION

6.1 What SINGULAIR contains?

In addition to the active ingredient the medicine also contains:

Each 10-mg film-coated tablet contains also:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate.

The film coating consists of:

Hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, yellow ferric oxide, carnauba wax and red ferric oxide.

Each 4-mg and 5-mg chewable tablet also contains :

Mannitol, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, artificial cherry flavor, magnesium stearate, aspartame, and red ferric oxide.

Each sachet of 4-mg oral granules also contains :

Mannitol, hydroxypropyl cellulose, and magnesium stearate.

Please note that the 10 mg film-coated tablets contain lactose. Each **SINGULAIR** 10 mg tablet contains 89.3 mg of lactose monohydrate.

Please note that the 4 mg and 5 mg chewable tablets contain aspartame, which is a source of phenylalanine. Each 4 mg chewable tablet contains 0.674 mg phenylalanine and each 5 mg chewable tablet contains 0.842 mg phenylalanine.

6.2 What **SINGULAIR** looks like and contents of the package

SINGULAIR 4 mg granules for kiddies are white, granular, coarse, free flowing homogeneous solid, with no extraneous particles present.

SINGULAIR 4 mg chewable tablets for pre-school kids are pink, oval, biconvex tablets with **SINGULAIR** debossed on one side and MSD 711 on the other.

SINGULAIR 5 mg chewable tablets are pink, round, biconvex tablets with **SINGULAIR** engraved on one side and MSD 275 on the other.

SINGULAIR 10 mg tablets are beige, rounded square, film-coated tablets with **SINGULAIR** engraved on one side and MSD 117 on the other.

Pack sizes:

SINGULAIR 4 mg granules for kiddies: 7, 10, 28, 30 sachets per pack.

SINGULAIR 4 mg chewable tablets for pre-school kids: 7, 10, 28, 30 chewable tablets per pack.

SINGULAIR 5 mg chewable tablets: 7, 10, 28, 30 chewable tablets per pack.

SINGULAIR 10 mg tablets: 7, 10, 28, 30 tablets per pack.

Not all pack sizes may be marketed.

License holder and address:

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Manufacturer: Organon LLC, NJ USA

Revised in January 2024.

Drug registration no. listed in the official registry of the Ministry of Health:

SINGULAIR 4 mg granules for kiddies: 130.14.30912

SINGULAIR 4 mg chewable tablets for pre-school kids: 121.67.30155

SINGULAIR 5 mg chewable tablets: 109.90.29316

SINGULAIR 10 mg tablets: 109.91.29317