

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

This medicine can be sold under doctor's prescription only

<b>SINGULAIR® 4mg GRANULES FOR KIDDIES</b>	<b>SINGULAIR® 4mg CHEWABLE TABLETS FOR PRE-SCHOOL KIDS</b>	<b>SINGULAIR® 5mg CHEWABLE TABLETS</b>	<b>SINGULAIR® 10mg TABLETS</b>
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Each sachet of granules contains: Montelukast 4 mg (as sodium salt)

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

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

Each tablet contains: Montelukast 10 mg (as sodium salt)

For a list of inactive ingredients please refer to section 6.

**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.

**1. WHAT SINGULAIR IS AND WHAT IT IS USED FOR?**

**1.1 What is 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.

**1.2 What is SINGULAIR used for?**

**SINGULAIR** is indicated for the treatment of chronic asthma, including the 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.

**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 sensitive (allergic) to the active substance or any of the other ingredients of the medicine.

### 2.2 Special Warnings concerning use of SINGULAIR

**Before starting treatment with SINGULAIR, tell your doctor:**

- about any medical problems or allergies you or your child has now or has had including allergy to Aspirin.
- If you are sensitive to any type of food or medicine
- If you are suffering or have suffered in the past from impaired function of the liver
- If you are pregnant, plan to become pregnant or if you are breast feeding

#### **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.
- Rarely, patients taking **SINGULAIR** have experienced a condition that includes a combination of certain symptoms that do not go away or that get worse. These symptoms may include:
  - a flu-like illness
  - rash
  - a feeling of pins and needles or numbness of arms or legs
  - breathing difficulties
  - severe inflammation (pain and swelling) of the sinuses (sinusitis)These have occurred usually, but not always, in patients who were taking oral corticosteroid pills for asthma and those corticosteroids were being slowly lowered or stopped. Although **SINGULAIR** has not been shown to cause this condition, you must tell your doctor right away if you develop one or more of these symptoms.
- Behavior and mood-related changes have been reported in patients taking **SINGULAIR**. If you or your child experience these changes while taking **SINGULAIR** (see section 4, "Possible Side Effects"), tell your doctor.

### 2.3 Taking Other Medicines

**If you take or have taken other medicines recently, including non-prescription medicines and nutritional supplements, or if you have just finished treatment with another medicine, inform the attending doctor or pharmacist, in order to prevent hazards or inefficacy arising from drug interactions.**

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

Do not take this medicine without consulting a doctor before starting treatment: if you are pregnant, intend to become pregnant, or breastfeeding.

### 2.6 Use in Children

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.

## 2.7 Driving and using machines

**SINGULAIR** is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medications may vary. Certain side effects (such as dizziness and drowsiness), that have been reported very rarely with **SINGULAIR** may affect some patients' ability to drive or operate machinery.

## 2.8 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).

If your child has phenylketonuria, you should note that 5 mg chewable tablets and 4 mg chewable tablets contain aspartame, which is a source of phenylalanine (see section 6).

## 3. HOW DO YOU USE **SINGULAIR**?

Always take **SINGULAIR** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

Do not chew! Swallow the tablet, with some water and without regard to meals.

#### **SINGULAIR 4 mg and 5 mg chewable tablets**

Chew the tablet before swallowing, without regard to meals.

#### **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 take more **SINGULAIR** than you should**

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.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

#### **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, and 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.

#### **How can you contribute to the success of the treatment?**

Complete the full course of treatment as instructed 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.

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.

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**.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, **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.

**Refer to the doctor immediately if you or your child develop the following side effects while using Singulair:**

- Behavior and mood-related changes [agitation including aggressive behavior or hostility, depression, disorientation (confusion), attention problems, bad or vivid dreams, feeling anxious, hallucinations (seeing or hearing things that are not really there), trouble sleeping, irritability, memory problems, restlessness, sleep walking, suicidal thoughts and actions (including suicide), tremor].
- Increase in certain white blood cells (eosinophils ) and possible inflamed blood vessels throughout the body (systemic vasculitis). The symptoms of these conditions may include: a flu-like illness, rash, a feeling of pins and needles or numbness of arms or legs and severe inflammation (pain and swelling) of the sinuses (sinusitis).

These side effects can happen rarely in people with asthma who take **SINGULAIR** or in people who also take steroid medicines by mouth, while the dose is being lowered or the administration is being stopped.

**SINGULAIR** is generally well-tolerated. In studies, the most common side effects reported were:

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

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

- 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]

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

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

#### **ADVERSE REACTIONS AND DRUG INTERACTIONS IN CHILDREN AND INFANTS:**

Parents must inform the attending doctor about any side effect, as well as any additional medicine being taken by a child.

See above for details of special side effects and drug interactions.

#### **5. HOW TO STORE SINGULAIR?**

Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach 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) which is stated on pack. 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 below 25°C.

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

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

Do not store different medications in the same package.

#### **6. FURTHER INFORMATION**

##### **6.1 What SINGULAIR contains?**

The active substance is montelukast.

The other ingredients are:

##### **Each 10-mg film-coated tablet contains the following inactive ingredients:**

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

The film coating consists of:

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

##### **Each 4-mg and 5-mg chewable tablet contains the following inactive ingredients:**

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

##### **Each sachet of 4-mg oral granules contains the following inactive ingredients:**

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 pack**

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

**SINGULAIR 4 mg chewable tablets** 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:** 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.

### **Marketing authorization holder:**

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O. Box 7121, Petah-Tikva 49170.

This leaflet was checked and approved by the Ministry of Health in June 2015.

### **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