

## SINGULAIR JUNIOR

5mg chewable tablets

MONTELUKAST

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

---

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

---

### What is in this leaflet?

1. What SINGULAIR JUNIOR is and what it is used for
2. Before you take SINGULAIR JUNIOR
3. How to take SINGULAIR JUNIOR
4. Possible side effects
5. How to store SINGULAIR JUNIOR
6. Further information

#### *1. WHAT SINGULAIR JUNIOR IS AND WHAT IS IT USED FOR*

##### **What SINGULAIR JUNIOR is**

SINGULAIR JUNIOR is a leukotriene receptor antagonist that blocks substances called leukotrienes.

##### **How SINGULAIR JUNIOR works**

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, SINGULAIR JUNIOR improves asthma symptoms and helps control asthma.

##### **When SINGULAIR JUNIOR should be used**

Your doctor has prescribed SINGULAIR JUNIOR to treat asthma, preventing your asthma symptoms during the day and night.

- SINGULAIR JUNIOR is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- SINGULAIR JUNIOR may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- SINGULAIR JUNIOR also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how SINGULAIR JUNIOR should be used depending on the symptoms and severity of your or your child's asthma.

### **What is asthma?**

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

## **2. BEFORE YOU TAKE SINGULAIR JUNIOR**

Tell your doctor about any medical problems or allergies you or your child has now or has had.

### **Do not take SINGULAIR JUNIOR**

- if you or your child is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before you or your child take SINGULAIR JUNIOR.

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral SINGULAIR JUNIOR is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. SINGULAIR JUNIOR should not be used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You or your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

### **Children and adolescents**

Do not give this medicine to children less than 6 years of age.

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

### **Other medicines and SINGULAIR JUNIOR**

Tell your doctor or pharmacist if you or your child are taking or have recently taken or might take any other medicines including those obtained without a prescription.

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

Tell your doctor if you or your child is taking the following medicines before starting SINGULAIR JUNIOR:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

### ***SINGULAIR JUNIOR with food and drink***

SINGULAIR JUNIOR 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

### ***Pregnancy and breast-feeding***

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking SINGULAIR JUNIOR.

### ***Pregnancy***

Your doctor will assess whether you can take SINGULAIR JUNIOR during this time.

### ***Breast-feeding***

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

### ***Driving and using machines***

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

### ***SINGULAIR JUNIOR 5mg chewable tablets contain aspartame, a source of phenylalanine***

If you or your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each SINGULAIR JUNIOR 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

## ***3. HOW TO TAKE SINGULAIR JUNIOR***

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You or your child should take only one chewable tablet of SINGULAIR JUNIOR once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

### **For children 6 to 14 years of age:**

The recommended dose is one SINGULAIR JUNIOR 5 mg chewable tablet daily to be taken in the evening.

If you or your child is taking SINGULAIR JUNIOR, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

SINGULAIR JUNIOR 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

***If you or your child takes more SINGULAIR JUNIOR than you should***

Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

***If you forget to take SINGULAIR JUNIOR or give SINGULAIR JUNIOR to your child***

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

Do not take a double dose to make up for a forgotten dose.

***If you or your child stops taking SINGULAIR JUNIOR***

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

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

#### ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with SINGULAIR JUNIOR 5 mg chewable tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to SINGULAIR JUNIOR were:

- headache

Additionally, the following side effect was reported in clinical studies with Singulair 10 mg film-coated tablets:

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with Singulair than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention: Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people Uncommon: may affect up to 1 in 100 people Rare: may affect up to 1 in 1,000 people Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Additionally, while the medicine has been on the market, the following have been reported:

- upper respiratory infection (*Very common*)
- increased bleeding tendency (*Rare*)
- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (*Uncommon*)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive

behaviour or hostility, depression (*Uncommon*); tremor, disturbance in attention, memory impairment (*Rare*); hallucinations, disorientation, suicidal thoughts and actions (*Very rare*)

- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*), swelling (inflammation) of the lungs (*Very rare*)
- diarrhoea, nausea, vomiting (*Common*); dry mouth, indigestion (*Uncommon*)
- hepatitis (inflammation of the liver) (*Very rare*)
- rash (*Common*); bruising, itching, hives (*Uncommon*); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); weakness/tiredness, feeling unwell, swelling (*Uncommon*)

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms (See section 2).

### **Reporting of side effects**

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (See details below). By reporting side effects you can help provide more information on the safety of this medicine.

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

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister after EXP. The first two numbers indicate the month; the last four numbers indicate the year. The expiry date refers to the last date of that month.
- Store in the original package in order to protect from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. FURTHER INFORMATION**

### **What SINGULAIR JUNIOR contains**

The active substance is montelukast. Each chewable tablet contains montelukast sodium which corresponds to 5 mg of montelukast.

The other ingredients are:

- Mannitol, microcrystalline cellulose, hypolose (E 463), red ferric oxide (E 172), croscarmellose sodium, cherry flavour, aspartame (E 951), and magnesium stearate.

### **What SINGULAIR JUNIOR looks like and contents of the pack**

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

Blisters in packages of: 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140, and 200 tablets. Blisters (unit dose), in packages of: 49x1, 50x1 and 56x1 tablets

Not all pack sizes may be marketed.

***Marketing Authorisation Holder***

Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

***Manufacturer***

Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland, NE23 3JU, UK.