

Read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to the others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What SINGULAIR 4-mg granules is and what it is used for
2. Before you take SINGULAIR 4-mg granules
3. How to take SINGULAIR 4-mg granules
4. Possible side effects
5. Storing SINGULAIR 4-mg granules

SINGULAIR® 4 mg granules
(montelukast)

Each sachet contains as active substance montelukast (in sodium salt form) 4 mg.
The excipients are mannitol, hydroxypropyl cellulose and magnesium stearate.

License holder:

MERCK SHARP & DOHME DE ESPAÑA, S.A.
C/ Josefa Valcárcel, 38
28027 - MADRID

Manufacturing responsible:

MERCK SHARP & DOHME, B.V.
Waarderweg 39
2031 BN, Haarlem
NETHERLANDS

1. WHAT SINGULAIR 4-mg GRANULES IS AND WHAT IT IS USED FOR

SINGULAIR 4-mg granules is available in packages of 28 sachets.

SINGULAIR belongs to a group of drugs called leukotriene receptor antagonists.

SINGULAIR 4-mg granules is used for the treatment of asthma in children 6 months to 5 years old who are not adequately controlled on their medication and need additional therapy. SINGULAIR 4-mg granules also helps prevent the narrowing of airways triggered by exercise.

2. BEFORE YOU TAKE SINGULAIR 4-mg GRANULES

Do not take SINGULAIR 4-mg:

- If your child is allergic to this medication or to any of its components.

Take special care with SINGULAIR 4-mg:

If during treatment with SINGULAIR 4-mg granules the child's asthma symptoms get worse, you should contact your doctor immediately.

If a child on anti-asthma medicines develops a combination of symptoms including a flu-like illness, pins and needles or numbness of arms or legs, and/or rash, you should consult your doctor.

If a child has an acute asthma attack:

The appropriate treatment for an acute asthma attack is an inhalation drug (short-acting β -agonist) that your doctor has prescribed for that purpose.

If an acute asthma attack occurs in a child **not** taking SINGULAIR 4-mg granules, SINGULAIR 4-mg granules should never be used to treat the acute asthma attack.

However, in a child treated with SINGULAIR 4-mg granules, it is important that the child continue taking SINGULAIR 4-mg granules daily as prescribed by your doctor, even if the child has an asthma attack.

Taking SINGULAIR 4-mg with food and drink:

SINGULAIR 4-mg granules can be taken without regard to the timing of food intake.

SINGULAIR 4-mg granules is not intended to be dissolved in liquid. However, your child may take liquids after swallowing the SINGULAIR 4-mg granules.

Taking other medicines:

In general, SINGULAIR 4-mg granules does not interfere with other medicines that the child may be taking. It is important, however, to tell the doctor about all drugs that the child is using or you plan the child to use, including those obtained without a prescription. In particular, tell your doctor if the child is taking phenobarbital, phenytoin or rifampicin.

Please inform your doctor or pharmacist if the child is taking or has recently taken any other medicines - even those not prescribed.

3. HOW TO TAKE SINGULAIR 4-mg GRANULES

Follow these instructions unless your doctor has given you different indications.

Inform your doctor about any medical problem or allergy the child has or has had.

Remember to give the child the medicine.

SINGULAIR 4-mg granules should be administered as prescribed by the doctor.

Dosage for children 6 months to 5 years of age: One sachet of 4-mg granules daily to be taken in the evening.

The SINGULAIR 4-mg granules is for children 6 months to 5 years old. Safety and effectiveness of SINGULAIR in children less than 6 months old have not been established.

Since SINGULAIR 4-mg granules treatment is a chronic maintenance treatment, it is important that the child continue taking SINGULAIR 4-mg granules daily as prescribed by your doctor, even when the child has no symptoms or if he has an episode of asthma attack (in the latter case, the appropriate treatment should be used to treat the asthma attack).

It is important that the child take all asthma medications prescribed by your doctor. SINGULAIR 4-mg granules should not be substituted for other asthma medications your doctor has prescribed for your child.

If you have the impression that the effect of SINGULAIR 4-mg granules is too strong or too weak, talk to your doctor or pharmacist.

How to give SINGULAIR 4-mg to the child:

Do not open the sachet until ready to use.

SINGULAIR 4-mg granules can be given either:

- directly in the mouth;
 - OR
 - mixed with a spoonful of cold or room temperature soft food (for example, applesauce, ice cream, carrots and rice).
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- Mix all of the contents of the SINGULAIR 4-mg granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.

- Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes).
IMPORTANT: Never store any granule/food mixture for use at a later time.

SINGULAIR 4-mg granules is not intended to be dissolved in liquid. However, your child may take liquids after swallowing the SINGULAIR 4-mg granules.

SINGULAIR 4-mg granules can be taken without regard to the timing of food intake.

If you take more SINGULAIR 4-mg than you should:

The most frequent symptoms reported with overdosage in children include thirst, excessive drowsiness, dilated pupils, hyperactivity and abdominal pain.

In case of overdosage or accidental intake consult the Information Service of Toxicology. Telephone: 91 562 04 20. Also contact your doctor immediately.

If you forget to take SINGULAIR 4-mg:

If the child misses a dose, just resume the usual schedule of one sachet once daily. Do not give the child a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SINGULAIR 4-mg granules may have side effects.

SINGULAIR is generally well-tolerated. In studies, the most commonly reported side effects thought to be related to SINGULAIR were abdominal pain, headache, thirst, diarrhoea, hyperactivity, asthma, scaly and itchy skin, and rash. Additionally, the following have been reported very rarely: allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, itching, and hives; tiredness, restlessness, agitation including aggressive behavior, irritability, dizziness, drowsiness, hallucinations, dream abnormalities, including nightmares and trouble sleeping, pins and needles/numbness, seizure; feeling unwell, joint or muscle pain, muscle cramps, dry mouth, nausea, vomiting, indigestion, diarrhoea, hepatitis; increased bleeding tendency, bruising, palpitations; and swelling.

These were usually mild and occurred as often in patients treated with SINGULAIR or placebo (a pill containing no medication).

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SINGULAIR 4-mg GRANULES

Keep out of the reach and sight of children.

Store in the original package.

Expiration

Do not use SINGULAIR 4-mg granules after the expiry date stated on the package.

This leaflet was approved on February 2004.