

Package leaflet: Information for the user

Singulair® Paediatric 4 mg Granules montelukast

Read all of this leaflet carefully before you give this medicine to your child because it contains important information.

- 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Singulair Paediatric is and what it is used for
2. What you need to know before your child takes Singulair Paediatric
3. How to take Singulair Paediatric
4. Possible side effects
5. How to store Singulair Paediatric
6. Contents of the pack and other information

1. What Singulair Paediatric is and what it is used for

What Singulair Paediatric is

Singulair Paediatric is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Singulair Paediatric works

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

When Singulair Paediatric should be used

Your doctor has prescribed Singulair Paediatric to treat your child's asthma, preventing asthma symptoms during the day and night.

- Singulair Paediatric is used for the treatment of 6 months to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Singulair Paediatric may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 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 Paediatric also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Singulair Paediatric should be used depending on the symptoms and severity of 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. What you need to know before your child takes Singulair Paediatric

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

Do not give Singulair Paediatric to your child

- if he/she 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 give Singulair Paediatric to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Singulair Paediatric is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child take all asthma medications prescribed by your doctor. Singulair Paediatric should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops 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.

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 his/her asthma worse

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If you develop such symptoms while taking montelukast, you should contact your doctor.

Children and adolescents

Do not give this medicine to children less than 6 months 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 Paediatric

Tell your doctor or pharmacist if your child is taking or has recently been given or might be given any other medicines including those obtained without a prescription.

Some medicines may affect how Singulair Paediatric works, or Singulair Paediatric may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Singulair Paediatric:

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

Singulair Paediatric with food and drink

Singulair Paediatric granules can be taken without regard to the timing of food intake.

Pregnancy and breast-feeding

This subsection is not applicable for the Singulair Paediatric 4 mg granules since they are intended for use in children 6 months to 5 years of age.

Driving and using machines

This subsection is not applicable for the Singulair Paediatric 4 mg granules since they are intended for use in children 6 months to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Singulair 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 may affect some patients' ability to drive or operate machinery.

Singulair Paediatric contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. How to take Singulair Paediatric

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

- This medicine is to be given to a child under adult supervision. Your child should take Singulair Paediatric every evening.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 6 months to 5 years of age:

The recommended dose is one sachet of Singulair Paediatric 4 mg granules to be taken by mouth each evening.

If your child is taking Singulair Paediatric, be sure that your child does not take any other products that contain the same active ingredient, montelukast.

How should I give Singulair Paediatric granules to my child?

This medicine is for oral use.

- Do not open the sachet until ready to use
- Singulair Paediatric 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).
- Mix all of the contents of the Singulair Paediatric 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 Paediatric granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the Singulair Paediatric granules.
- Singulair Paediatric granules can be taken without regard to the timing of food intake.

If your child takes more Singulair Paediatric than he/she should

Contact your child's 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 give Singulair Paediatric to your child

Try to give Singulair Paediatric as prescribed. However, if your child misses a dose, just resume the usual schedule of one sachet once daily.

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

If your child stops taking Singulair Paediatric

Singulair Paediatric can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Singulair Paediatric for as long as your doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's 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 Paediatric 4 mg granules, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Singulair Paediatric were:

- diarrhoea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

Additionally, the following side effects were reported in clinical studies with either Singulair 10 mg film-coated tablets, Singulair Paediatric 5 mg or 4 mg chewable tablets:

- abdominal pain
- headache
- thirst

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

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects with your child, which may be serious, and for which your child may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure

Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- 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) (see section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Singulair Paediatric

- 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 sachet 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.
- Do not store above 25°C. 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. Contents of the pack and other information

What Singulair Paediatric contains

- The active substance is montelukast. Each sachet of granules contains montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredients are: Mannitol (E 421), hypolose (E 463), and magnesium stearate.

What Singulair Paediatric looks like and contents of the pack

4 mg Singulair Paediatric granules are white granules.

Cartons of 7, 20, 28 and 30 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder:
Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
Dublin, D01 V4A3
Ireland.

The Manufacturer:
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

Information is given by

The Asthma Society of Ireland, 42 - 43 Amiens Street, Dublin 1, tel: 01 817 8886. Alternatively call the Asthma Adviceline on 1850 44 5464.

(The Asthma Society of Ireland is an independent charity working to conquer asthma and is not associated with Organon Pharma (Ireland) Limited.)

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxemburg, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovak Republic, Spain, Sweden,

Singulair

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