

Package leaflet: Information for the user

Singulair® Paediatric 4 mg chewable tablets

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 2 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.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with Singulair Paediatric (see section 4). If your child develops such symptoms while taking Singulair Paediatric, you should consult your child's doctor.

Children and adolescents

Do not give this medicine to children less than 2 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 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 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

This subsection is not applicable for the Singulair Paediatric 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for the Singulair Paediatric 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

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

Singulair Paediatric 4 mg chewable tablets contain aspartame, a source of phenylalanine

If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each 4 mg chewable tablet contains phenylalanine (equivalent to 0.674 mg phenylalanine per 4 mg chewable tablet).

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. For children who have problems consuming a chewable tablet, an oral granule formulation is available.
- Your child should take only one chewable tablet of Singulair Paediatric once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 2 to 5 years of age:

The recommended dose is one 4 mg chewable tablet daily to be taken in the evening.

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

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Singulair Paediatric 4 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 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 chewable tablet 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 chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Singulair Paediatric were:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with Singulair 10 mg film-coated tablets and 5 mg chewable tablets:

- headache

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, which may be serious, and for which you 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 or nurse. 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 blister and carton 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. Contents of the pack and other information

What Singulair Paediatric contains

- The active substance is montelukast. Each chewable tablet contains montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredients are: mannitol (E 421), microcrystalline cellulose, hypolose (E 463), red ferric oxide (E 172), croscarmellose sodium, cherry flavour, aspartame (E 951), and magnesium stearate.

What Singulair Paediatric looks like and contents of the pack

Singulair Paediatric 4 mg chewable tablets are pink, oval, biconvex with SINGULAIR engraved on one side and MSD 711 on the other.

Singulair Paediatric 4 mg chewable tablets are available in blister packs of 28 tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Merck Sharp & Dohme BV, Waarderweg 39, PO Box 581, 2031 BN, Haarlem, The Netherlands.

Parallel Product Authorisation Number

PPA 465/111/3

Singulair is a registered trademark of Merck Sharp & Dohme Corp.

Information is given by:

In Ireland: The Asthma Society of Ireland, 42-43 Amiens Street, Dublin 1, tel: 01 8178886. Alternatively call the Asthma advice line on 1850 44 5464.

(The Asthma Society of Ireland is an independent charity working to conquer asthma and is not associated with Merck Sharp & Dohme Limited.)

This medicinal product is authorised in the Member States of the EEA under the following names:

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

Singulair

This leaflet was last revised in July 2020.