

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINGULAIR® Paediatric 4 mg chewable tablets

montelukast

Read all of this leaflet carefully before your child starts taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What SINGULAIR Paediatric is and what it is used for
2. Before SINGULAIR Paediatric is taken
3. How to take SINGULAIR Paediatric
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1. What SINGULAIR paediatric is and what it is used for

SINGULAIR Paediatric is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, SINGULAIR Paediatric improves asthma symptoms and helps control asthma. 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. Before SINGULAIR paediatric is taken

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 (hypersensitive) to montelukast or any of the other ingredients of SINGULAIR Paediatric (see 6. Further information).

Take special care with SINGULAIR Paediatric

- 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.

Taking other medicines

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

Please tell your doctor or pharmacist if your child is taking or has recently taken other medicines, including those obtained without a prescription.

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)

Taking 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 two 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, however the following information is relevant to the active ingredient, montelukast.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking SINGULAIR. Your doctor will assess whether you can take SINGULAIR during this time.

Use in breast-feeding

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

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 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 very rarely with SINGULAIR may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients of SINGULAIR Paediatric

SINGULAIR Paediatric 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 SINGULAIR Paediatric 4 mg chewable tablet contains phenylalanine (equivalent to 0.674 mg phenylalanine per 4 mg chewable tablet)

3. How to take SINGULAIR paediatric.

- 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 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.
- Always have your child take SINGULAIR Paediatric as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth

For children 2 to 5 years of age:

One SINGULAIR Paediatric 4 mg chewable tablet daily to be taken in the evening. 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 is taking SINGULAIR Paediatric, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

For children 2 to 5 years old, SINGULAIR Paediatric 4 mg chewable tablets and 4 mg granules are available.

For children 6 to 14 years old, SINGULAIR Paediatric 5 mg chewable tablets are available. The SINGULAIR Paediatric 4 mg chewable tablet is not recommended below 2 years of age.

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 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 your child 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 product, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, SINGULAIR Paediatric 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 (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) 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).

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

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 rash, 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 (*Rare*); hallucinations, suicidal thoughts and actions (*Very rare*)]
- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, nausea, vomiting (*Common*); dry mouth, indigestion (*Uncommon*)
- hepatitis (inflammation of the liver) (*Very rare*)
- bruising, itching, hives (*Uncommon*); tender red lumps under the skin most commonly on your shins (erythema nodosum) (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); 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 your child gets one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5. How to store SINGULAIR paediatric

- Keep out of the reach and sight of children.
- Do not use this medicine after the date shown by the six numbers following EXP on the outer carton and blister. The first two numbers indicate the month; the last four numbers indicate the year. This medicine expires at the end of the month shown.
- Store in the original package in order to protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What SINGULAIR Paediatric contains

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredients are:
Mannitol, microcrystalline cellulose, hypolose (E 463), red ferric oxide (E 172), croscarmellose sodium, cherry flavour, aspartame (E951), 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. Blisters in packages of: 28, and 56

Manufacturer

SINGULAIR Paediatric 4 mg chewable tablets are manufactured by Merck Sharp & Dohme BV, Waarderweg 39, PO Box 581, 2003 PC or 2031 BN Haarlem, The Netherlands.

Procured from within the EU by the Parallel Product Authorisation Holder Primecrown 2010 Ltd, Unit 4/5 Northolt Trading Estate, Northolt, Middlesex UB5 5QS UK
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Information is given by:

In UK: Asthma UK, Providence House, Providence Place, London N1 0NT. Alternatively phone the Asthma UK Adviceline on 08457 010203, Monday to Friday 9 am to 5 pm, calls charged at local rate.

In Ireland: The Asthma Society of Ireland, Eden House, 15-17 Eden Quay, Dublin 1. Alternatively phone The Asthma Live Line on 01 8788122, Monday, Wednesday, Thursday 10am to 1pm, or 01 8788511 9am to 5pm, or The Asthma Line on callsave 1850 44 5464.

(The Asthma UK and The Asthma Society of Ireland are independent charities working to conquer asthma and are 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, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy,

Latvia, Lithuania, Luxemburg, Malta, Netherlands, Norway, Poland,
Portugal, Romania, Slovenia, Slovak Republic, Spain, Sweden,
United Kingdom

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