

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINGULAIR® Paediatric 5 mg chewable tablets

montelukast

Read all of this leaflet carefully before you or your child start 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 you or your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your or 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 you 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 asthma, preventing your asthma symptoms during the day and night.

- SINGULAIR Paediatric is used for the treatment of 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 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 Paediatric also helps prevent the narrowing of airways triggered by exercise. Your doctor will determine how SINGULAIR Paediatric should be used depending on the symptoms and severity of you 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 paediatric

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

Do not take SINGULAIR Paediatric if you or your child

- 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 you or 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 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 Paediatric 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 acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Use in children

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

For children 6 to 14 years old, SINGULAIR Paediatric 5 mg chewable tablets are available.

Taking other medicines

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

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

Tell your doctor if you or 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 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

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 breast-feeding or intend to breast-feed.

Driving and using machines

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 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

3. How to take SINGULAIR paediatric

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

For children 6 to 14 years of age:

One SINGULAIR Paediatric 5 mg chewable tablet daily to be taken in the evening. SINGULAIR Paediatric 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 is taking SINGULAIR Paediatric, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

If you or your child takes more SINGULAIR Paediatric 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.

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If you forget to take SINGULAIR Paediatric or give SINGULAIR Paediatric to your child

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

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

If you or your child stops taking SINGULAIR Paediatric

SINGULAIR Paediatric 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 Paediatric 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 product, ask your 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 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 Paediatric 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 (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

you get 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 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. Store below 30 °C
- 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 5 mg of montelukast.
- The other ingredients are:
Mannitol, microcrystalline cellulose, hypromellose (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 5 mg chewable tablets are pink, round, biconvex with SINGULAIR engraved on one side, MSD 275 on the other.

Blisters in packages of: 28, and 56,

Manufacturer

SINGULAIR Paediatric 5 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

Repackaged by Primecrown Ltd, Unit 4/5 Northolt Trading Estate

Northolt, Middlesex UB5 5QS UK

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, Denmark, Finland, France, Greece,

Spain, Sweden, Germany, Ireland, UK, Italy, Luxemburg,
Netherlands, Portugal

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