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 because it contains important information for you or your child.
- 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 you or 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 or your child's.
- If you or your child get 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

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2. What you need to know before you take Singulair Paediatric
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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 asthma, preventing your asthma symptoms during the day and night.

- Singulair Paediatric is used for the treatment of paediatric patients 6 to 14 years of age 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 your 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. What you need to know 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 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 or your child take 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 acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your 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 (see section 4). If you or your child develop such symptoms while taking Singulair, you should consult your doctor.

Children and adolescents
Do not give this medicine to children less than 6 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 you or your child are taking or have recently taken or might take any other medicines including those obtained without a prescription.

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

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)

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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Singulair Paediatric.

Pregnancy
Your doctor will assess whether you can take Singulair Paediatric during this time.

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

Driving and using machines
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 5 mg chewable tablets contain aspartame, a source of phenylalanine and sodium
If you or your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

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

3. How to take Singulair Paediatric

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- You or 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 you or your child has no symptoms or has an acute asthma attack.

For children 6 to 14 years of age:
The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.

If you or your child are taking Singulair Paediatric, be sure that you or your child do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.
The tablets are to be chewed before swallowing.
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 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.

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 chewable 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 medicine, ask your 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 5 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:
- 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).

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 or 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 you or your child get 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 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 5 mg of montelukast.
- The other ingredients are:
  Mannitol (E 421), microcrystalline cellulose, hyprolose (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
5 mg Singulair Paediatric chewable tablets are pink, round, biconvex, plain on one side and 275 on the other.
Blisters in packages of: 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140, and 200 tablets.
Blisters (unit dose), in packages of: 49x1, 50x1 and 56x1 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder and manufacturer:
Organon Pharma (UK) Limited, Shotton Lane, Cramlington, NE23 3JU, UK.

Information is given by:
Asthma UK, 18 Mansell Street, London, E1 8AA. Alternatively phone the Asthma UK Helpline on 0300 222 5800, Monday to Friday, 9 am to 5 pm.

(Asthma UK is an independent charity working to conquer asthma and is not associated with Organon Pharma (UK) 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, United Kingdom, Italy, Luxemburg, Netherlands, Portugal
Singulair

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