

## Package leaflet: Information for the user

# Singulair® Paediatric 4mg chewable tablets (montelukast sodium)

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.

The name of your medicine is Singulair Paediatric 4mg chewable tablets but will be referred to as Singulair Paediatric throughout this leaflet.

### 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 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 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 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 contain aspartame, sodium and benzyl alcohol

This medicine contains 1.2mg aspartame in each 4mg chewable tablet which is equivalent to 0.674mg phenylalanine. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

This medicine contains up to 0.36mg benzyl alcohol per tablet.

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if your child has a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in the body and may cause side effects (called 'metabolic acidosis').

Do not use for more than a week in young children (less than 3 years old) unless advised by your doctor or pharmacist.

## 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 4mg 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 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 4mg 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 10mg film-coated tablets and 5mg chewable tablets:

- headache

These were usually mild and occurred at a greater frequency in patients treated with Singulair Paediatric 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 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](http://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 out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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. Contents of the pack and other information

### What Singulair Paediatric contains

The active ingredient in Singulair Paediatric is montelukast sodium.

Each chewable tablet contains montelukast sodium equivalent to 4mg montelukast.

The other ingredients are mannitol (E421), microcrystalline cellulose, hydroxypropylcellulose (E463), red ferric oxide (E172) croscarmellose sodium, cherry flavour containing benzyl alcohol (E1519), aspartame (E951) and magnesium stearate.

### What Singulair Paediatric looks like and contents of the pack

The tablet is pink, oval, bi-convex shaped engraved 'MSD 711' on one side and 'SINGULAIR' on the other.

Singulair Paediatric is available in a blister packs containing 28 tablets.

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

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK.

**Singulair® Paediatric 4mg chewable tablets;**  
**PL 18799/2117**

**POM**

Leaflet date: 23.01.2024

Singulair is the registered trademark of N.V. Organon.

**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 0208 515 3763 to  
obtain the leaflet in a format  
suitable for you.**

Information is given by:

**In UK:** 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, calls charged at local rate

(The Asthma UK is an independent charity working to conquer asthma and is not associated with B&S Healthcare).

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# Montelukast Paediatric 4mg chewable tablets (montelukast sodium)

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- 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.

The name of your medicine is Montelukast Paediatric 4mg chewable tablets but will be referred to as Montelukast Paediatric throughout this leaflet.

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## 1. What Montelukast Paediatric is and what it is used for

### What Montelukast Paediatric is

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

### How Montelukast Paediatric works

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

### When Montelukast Paediatric should be used

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

- Montelukast 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.
- Montelukast 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.
- Montelukast Paediatric also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast 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 Montelukast Paediatric

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

### Do not give Montelukast 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 Montelukast Paediatric to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 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. Montelukast 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 Montelukast Paediatric (see section 4). If your child develops such symptoms while taking Montelukast 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 Montelukast 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 Montelukast Paediatric works, or Montelukast Paediatric may affect how your child's other medicines work.

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

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

### Montelukast Paediatric with food and drink

Montelukast Paediatric 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 Montelukast Paediatric 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 Montelukast Paediatric 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.

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

### Montelukast Paediatric contain aspartame, sodium and benzyl alcohol

This medicine contains 1.2mg aspartame in each 4mg chewable tablet which is equivalent to 0.674mg phenylalanine. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

This medicine contains up to 0.36mg benzyl alcohol per tablet.

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if your child has a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in the body and may cause side effects (called 'metabolic acidosis').

Do not use for more than a week in young children (less than 3 years old) unless advised by your doctor or pharmacist.

## 3. How to take Montelukast 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 Montelukast 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 4mg chewable tablet daily to be taken in the evening.

If your child is taking Montelukast 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.

Montelukast Paediatric 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 Montelukast 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 Montelukast Paediatric to your child

Try to give Montelukast 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 Montelukast Paediatric

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

It is important for your child to continue taking Montelukast 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 Montelukast Paediatric 4mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast Paediatric were:

- abdominal pain
- thirst

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

- headache

These were usually mild and occurred at a greater frequency in patients treated with Montelukast Paediatric 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

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