

PACKAGE LEAFLET: INFORMATION FOR THE USER  
**SINGULAIR® PAEDIATRIC 5mg CHEWABLE TABLETS**  
 (montelukast sodium)

**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

1. What Singulair Paediatric is and what it is used for
2. What you need to know before you take 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 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](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.**
- Do not store above 30 °C. Store in the original package in order to protect from light and moisture.
- Do not use after the expiry date printed on the carton label or blister strip.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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

- Each chewable tablet contains montelukast sodium 5.2mg, which is equivalent to 5mg montelukast.
- Singulair Paediatric also contains the following inactive ingredients: mannitol, microcrystalline cellulose, hydroxypropyl cellulose (E 463), iron oxide red (E172), croscarmellose sodium, cherry flavor, aspartame (E951), and magnesium stearate.

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

- Singulair Paediatric is pink, round, biconvex tablets with Singulair Paediatric engraved on one side, MSD 275 on the other.
- Singulair Paediatric is available as blister packs of 28 tablets.

### Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

### Manufacturer

This product is manufactured by Merck Sharp & Dohme BV, Waarderweg 39, 2031 BN Haarlem, The Netherlands.

**POM** PL: 19488/1688

**Leaflet revision date:** 20 August 2021

**Blind or partially sighted? Is this leaflet hard to see or read? Call 02087997607 to obtain the leaflet in large print, tape, CD or Braille.**

*Singulair® is a registered trade mark of Merck Sharp & Dohme Corp., USA.*

*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, calls charged at local rate.

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

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## PACKAGE LEAFLET: INFORMATION FOR THE USER

**MONTELUKAST TABLETS PAEDIATRIC 5 mg CHEWABLE TABLETS**

(Montelukast Tablets sodium)

Your medicine is known as Montelukast Tablets Paediatric 5mg Chewable Tablets but will be referred to as Montelukast Tablets throughout the following leaflet.

**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**

1. What Montelukast Tablets is and what it is used for
2. What you need to know before you take Montelukast Tablets
3. How to take Montelukast Tablets
4. Possible side effects
5. How to store Montelukast Tablets
6. Contents of the pack and other information

**1. What Montelukast Tablets is and what it is used for****What Montelukast Tablets is**

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

**How Montelukast Tablets works**

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

**When Montelukast Tablets should be used**

Your doctor has prescribed Montelukast Tablets to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast Tablets 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.
- Montelukast Tablets 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.
- Montelukast Tablets also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Montelukast Tablets 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 Montelukast Tablets**

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

**Do not take Montelukast Tablets**

- if you or your child is allergic to Montelukast Tablets 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 Montelukast Tablets.

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.

- Oral Montelukast Tablets 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. Montelukast Tablets 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 Montelukast Tablets (see section 4). If you or your child develop such symptoms while taking Montelukast Tablets, 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 Montelukast Tablets**

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 Montelukast Tablets works, or Montelukast Tablets may affect how other medicines work.

Tell your doctor if you or your child is taking the following medicines before starting Montelukast Tablets:

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

**Montelukast Tablets with food and drink**

Montelukast Tablets 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 Montelukast Tablets.

**Pregnancy**

Your doctor will assess whether you can take Montelukast Tablets during this time.

**Breast-feeding**

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

**Driving and using machines**

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

**Montelukast Tablets 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 Montelukast Tablets**

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 Montelukast Tablets 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 Montelukast Tablets, 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. Montelukast Tablets 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 Montelukast Tablets 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 Montelukast Tablets or give Montelukast Tablets to your child**

Try to take Montelukast Tablets 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 Montelukast Tablets**

Montelukast Tablets can treat you or your child's asthma only if you or your child continues to take it.

It is important to continue taking Montelukast Tablets 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 Montelukast Tablets 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast Tablets were:

- headache

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

- abdominal pain

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

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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](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 Montelukast Tablets**

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
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- 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 Montelukast Tablets contains**

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- Montelukast Tablets is available as blister packs of 28 tablets.

#### **Product Licence holder**

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alpertons Lane, Wembley, HA0 1DX.

#### **Manufacturer**

This product is manufactured by Merck Sharp & Dohme BV, Waarderweg 39, 2031 BN Haarlem, The Netherlands.

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**Leaflet revision date:** 20 August 2021

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