

**FINAL TYPED PATIENT INFORMATION LEAFLET  
INFORMATION FOR THE PATIENT  
ABOUT SINGULAIR® (MONTELUKAST, MSD)**

***Read all of this leaflet carefully before you start using SINGULAIR***

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.*

**SCHEDULING STATUS**

S3

**PROPRIETARY NAME AND DOSAGE FORM**

**SINGULAIR®** 4 mg Chewable Tablets

(4 mg montelukast)

**WHAT SINGULAIR CONTAINS**

SINGULAIR (montelukast sodium, MSD) contains montelukast sodium as the active ingredient.

It is available as:

- a 4 mg chewable tablet for children 2 to 5 years old.

Each 4 mg chewable tablet contains 4 mg of montelukast.

In addition, SINGULAIR contains the following inactive ingredients:

SINGULAIR 4 mg contains: Artificial Cherry Flavour, Aspartame, Croscarmellose Sodium, Hydroxypropylcellulose, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Red Ferric Oxide.

SINGULAIR 4 mg Chewable Tablet is sugar free.

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**WHAT SINGULAIR IS USED FOR**

SINGULAIR is use for treatment of asthma

**Why has my doctor prescribed SINGULAIR?**

Your doctor has prescribed SINGULAIR to treat:

- Your child's asthma, including preventing asthma symptoms

**How does SINGULAIR treat asthma?**

SINGULAIR blocks substances in your child's lungs called leukotrienes that cause narrowing and inflammation of airways

**Why is compliance (giving your child medicine as prescribed) important?**

Having your child take his/her medicine as your doctor or health care provider instructs may help reduce the severity and frequency of your child's asthma attacks.

**BEFORE YOU TAKE SINGULAIR**

**Do not have your child take SINGULAIR:**

- if he/she is allergic to montelukast or any of the other ingredients of SINGULAIR.
- if he/she is under the age of 2 years, as safety and efficacy have not been demonstrated.

**Take special care with SINGULAIR**

It is important that your child continue taking SINGULAIR daily as prescribed by your doctor, even when your child has no symptoms or if your child has an asthma attack.

If your child's asthma symptoms get worse, you should contact your doctor immediately.

Oral tablets of SINGULAIR are not for the treatment of acute asthma attacks. If an attack occurs, your child should follow the instructions your doctor has given you for that situation.

If your child has phenylketonuria, you should note that the 4 mg chewable tablets contain aspartame, which is a source of phenylalanine (0,674 mg per 4 mg chewable tablet).

It is important that your child take all asthma medications prescribed by your doctor. SINGULAIR should not be substituted for other asthma medications your doctor has prescribed for your child.

If your child's asthma is known to be made worse by aspirin, do not give your child aspirin and other non-steroidal anti-inflammatory drugs.

**What should I tell my doctor before my child takes SINGULAIR?**

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

**Use in children**

SINGULAIR 4 mg chewable tablets are for children 2 to 5 years old.

**Pregnancy and Breast-feeding**

**If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.**

The safety of this preparation in pregnant and breast-feeding women has not been established. SINGULAIR has not been studied in pregnant women.

It is not known if SINGULAIR is excreted in human milk.

**Driving and using machinery**

SINGULAIR is not expected to affect your ability to drive a car or operate machinery.

**Taking other medicines with SINGULAIR**

In general, SINGULAIR does not interfere with other medicines that your child may be taking. It is important, however, to tell your doctor about all drugs that your child is using or plan to use, including those obtained without a prescription.

**If your child is taking other medicines on a regular basis including complementary or traditional medicines, the use of SINGULAIR with these medicines, may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.**

**HOW TO USE SINGULAIR****How should my child take SINGULAIR?**

Always take SINGULAIR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your child should take SINGULAIR once a day with or without food, as your doctor has prescribed. The dose for children 2 to 5 years old for the treatment of asthma is one 4 mg chewable tablet daily.

If you have the impression that the effect of SINGULAIR is too strong or too weak, talk to your doctor or pharmacist.

For patients with asthma, take SINGULAIR once a day in the evening.

It is important for your child to continue taking SINGULAIR for as long as your doctor prescribes it in order to maintain control of your child's asthma. SINGULAIR can treat your child's asthma only if your child continues to take it.

Do not share medicines prescribed for you with any other person.

#### **What should I do in case of an overdose?**

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most frequent symptoms reported with overdosage in children included abdominal pain, sleepiness, thirst, headache, vomiting and psychomotor hyperactivity
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#### **If your child forgets to take SINGULAIR**

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

Do not give your child a double dose to make up for the forgotten individual doses.

#### **POSSIBLE SIDE EFFECTS**

##### **What undesirable side effects may SINGULAIR have?**

Side effects generally did not require discontinuation of therapy.

The following drug-related adverse reactions in placebo-controlled clinical studies were reported commonly (greater than 1/100, less than 1/10) in patients with asthma treated with SINGULAIR and at a greater incidence than in patients treated with placebo:

	Paediatric Patients	Adult Patients	Paediatric Patients
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Body System Class	6 to 14 years old (one 8-week study; n=201)	15 years and older (two 12-week studies; n=795)	2 to 5 years old (one 12-week study; n=461)
General disorders and administration site conditions			thirst
Gastro-intestinal disorders		stomach pain	
Nervous system disorders	headache	headache	

Cumulatively, 338 paediatric patients 2 to 5 years of age were treated for 6 months or longer, and 256 patients for 12 months or longer. With prolonged treatment, the safety profile did not change in these patients either.

#### Post – Marketing Experience

The following side effects have been reported in post-marketing use:

**Blood and lymphatic systems disorders:** increased bleeding tendency.

**Immune system disorders:** allergic reactions including sudden life threatening allergic reactions; hepatic eosinophilic infiltration

**Psychiatric disorders:** abnormal dreams, seeing, feeling or hearing things that are not there, agitation including aggressive behaviour, depression, feeling anxious, inability to sleep, irritability, restlessness, suicidal thoughts and actions, tremor

**Nervous system disorders:** dizziness, drowsiness, pins and needles/decreased feeling or sensitivity (especially in the skin), seizure

**Cardiac disorders :** palpitations

**Respiratory, thoracic and mediastinal disorders:** nose bleeding

**Gastro-intestinal disorders:** diarrhoea, indigestion, nausea, vomiting

**Hepatobiliary disorders:** increased ALT and AST (liver enzymes), liver disease

**Musculoskeletal and connective tissues disorders:** joint pain, aching muscles including muscle cramps

**Skin and subcutaneous disorders:** swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; hives, itching, rash, bruising

**General disorders and administration site conditions:** swelling, fever.

*Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.*

**How can I learn more about SINGULAIR?**

You may obtain further information from your physician or pharmacist, who have more detailed information about SINGULAIR and your child's condition.

**STORING AND DISPOSING OF SINGULAIR****How long should I keep my child's medicine?**

Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

**How should I store SINGULAIR?**

Store at room temperature below 30 °C, protected from moisture and light.

Store all medicines out of reach and sight of children.

**PRESENTATION OF SINGULAIR**

SINGULAIR 4 mg chewable tablets are available in aluminium blister packs of 28 and 14.

**IDENTIFICATION OF SINGULAIR**

SINGULAIR 4 mg: A pink, oval, biconvex tablet with a cherry taste and odour. 'SINGULAIR' is engraved on one side and 'MSD 711' on the other.

**REGISTRATION NUMBER**

SINGULAIR 4 mg : 35/10.2.2/0397

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION.**

MSD (Pty) Ltd

16<sup>th</sup> Road

Halfway House

1685

Telephone number: 011 655 3000

**DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET**

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