

<b>SINGULAIR 5 mg and SINGULAIR 10 mg</b>	<b>APPROVED PATIENT INFORMATION LEAFLET (SR-PIN)</b>
<b>Submitted to MCC: 20 OCTOBER 2011</b>	<b>Version: Clean-Copy</b>

**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®** 5 mg Chewable Tablets

(5 mg montelukast)

**SINGULAIR®** 10 mg Film-coated Tablets

(10 mg montelukast)

**WHAT SINGULAIR CONTAINS**

SINGULAIR (montelukast sodium, MSD) contains montelukast sodium as the active ingredient. It is available as:

- a 10mg tablet for adults and adolescents 15 years and older.
- a 5mg chewable tablet for children 6 to 14 years old.

Each 10 mg tablet contains 10 mg montelukast and each 5 mg chewable tablet contains 5 mg montelukast.

In addition, SINGULAIR contains the following inactive ingredients:

SINGULAIR 5 mg contains:

Artificial Cherry Flavour, Aspartame, Croscarmellose Sodium, Hydroxypropylcellulose, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Red Ferric Oxide.

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SINGULAIR 10 mg contains:

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Carnauba Wax, Croscarmellose Sodium, Hydroxypropylcellulose, Lactose Monohydrate, Magnesium Stearate, Methylhydroxypropylcellulose, Microcrystalline Cellulose, Red Ferric Oxide, Titanium Dioxide, Yellow Ferric Oxide

SINGULAIR 5 mg is sugar free

SINGULAIR 10 mg contains lactose.

### **WHAT SINGULAIR IS USED FOR**

SINGULAIR is used for treatment of asthma.

### **Why has my doctor prescribed SINGULAIR?**

Your doctor has prescribed SINGULAIR to treat your asthma, including preventing your asthma symptoms.

In those adult asthmatic patients, in whom SINGULAIR is indicated in asthma, SINGULAIR may provide some symptomatic relief of seasonal allergic rhinitis.

### **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 (taking my medicine as prescribed) important?**

Taking your medicine as your doctor or health care provider instructs may help reduce the severity of your asthma, and the frequency of your asthma attacks.

### **BEFORE YOU TAKE SINGULAIR**

#### **Do not take SINGULAIR :**

- if you are allergic to montelukast or any of the other ingredients of SINGULAIR.

#### **Do not give your child SINGULAIR to take:**

- if he/she is allergic to montelukast or any of the other ingredients of SINGULAIR
- if he/she is under the age of 6 years, as safety and efficacy of 5 mg and 10 mg tablets have not been demonstrated.

### **Take special care with SINGULAIR**

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

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If your or your child's asthma symptoms get worse, or if you need to increase the use of your or your child's inhaled rescue medicine for asthma attacks, you should contact your doctor immediately.

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

If your child has phenylketonuria, you should note that the 5 mg chewable tablets contain aspartame, which is a source of phenylalanine (0,842 mg per 5 mg chewable tablet).

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

If your doctor has prescribed a medicine for you or your child to use before exercise, keep using that medicine unless your doctor tells you not to.

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

**What should I tell my doctor before I take SINGULAIR?**

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

**Use in children**

SINGULAIR 5 mg chewable tablets are for children 6 to 14 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**

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In general, SINGULAIR does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how SINGULAIR works, or SINGULAIR may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child are using or plan to use, including those obtained without a prescription.

**If you or your child are 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 I take SINGULAIR**

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

Take SINGULAIR once a day with or without food, as your doctor has prescribed.

- The dose for adults and adolescents 15 years and older for the treatment of asthma with or without seasonal allergic rhinitis is one 10 mg tablet daily.
- The dose for children 6 to 14 years old for the treatment of asthma is one 5 mg chewable tablet daily. SINGULAIR 5 mg has not been studied in seasonal allergic rhinitis in children with asthma

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 with or without seasonal allergic rhinitis, take SINGULAIR once a day in the evening.

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

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

Available Formulations:

- SINGULAIR 5 mg chewable tablets are available for treatment of children 6 to 14 years old.
- SINGULAIR 10 mg film-coated tablets are available for the treatment of adolescents 15 years of age and older and of adults.

### **If you take more SINGULAIR than you should**

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

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The most frequently occurring symptoms reported with overdosage in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting psychomotor hyperactivity.

**If you or your child forgets to take SINGULAIR**

Try to take SINGULAIR 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 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:

Body system class	Adult patients 15 years and older (two 12 week studies; n=795)	Paediatric Patients 6 to 14 years old (one 8 week study; n=201)
Nervous system disorder	Headache	Headache
Gastro-intestinal disorders	Abdominal pain	Abdominal pain

With prolonged treatment in clinical trials with a limited number of patients for up to 2 years for adults, and up to 6 months for paediatric patients 6 to 14 years of age, the safety profile did not change.

**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

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**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 condition.

#### **STORING AND DISPOSING OF SINGULAIR**

##### **How long should I keep my 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 5 mg chewable tablets are available in blister packs of 14 and 28.

SINGULAIR 10 mg tablets are available in blister packs of 14 and 28.

#### **IDENTIFICATION OF SINGULAIR**

SINGULAIR 5 mg: A pink, round, biconvex tablet with SINGULAIR engraved on one side and 'MSD 275' on the other.

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SINGULAIR 10 mg: A beige, rounded square film-coated tablet with SINGULAIR engraved on one side and 'MSD 117' on the other.

**REGISTRATION NUMBER**

SINGULAIR 5 mg : 32/10.2.2/0321

SINGULAIR 10 mg : 32/10.2.2/0322

**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**

3 JUNE 2011 (Revision (1): 20 December 2011)