

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

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

- *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® SPRINKLES

(4 mg montelukast)

WHAT SINGULAIR SPRINKLES CONTAINS

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

Each packet of 4 mg oral granules contains 4 mg of montelukast.

In addition, SINGULAIR SPRINKLES contains the following inactive ingredients:

Hydroxypropylcellulose, Magnesium Stearate, Mannitol.

SINGULAIR SPRINKLES is sugar free

® Registered Trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA.
COPYRIGHT © 2010 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA. All rights reserved.

WHAT SINGULAIR SPRINKLES IS USED FOR

SINGULAIR SPRINKLES is used for treatment of asthma.

Why has my doctor prescribed SINGULAIR SPRINKLES?

Your doctor has prescribed SINGULAIR SPRINKLES to treat :

- Your child's asthma, including preventing asthma symptoms.

How does SINGULAIR SPRINKLES treat asthma?

SINGULAIR SPRINKLES 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 YOUR CHILD TAKES SINGULAIR SPRINKLES**Do not have your child take SINGULAIR SPRINKLES:**

- If he/she is allergic to montelukast or any of the other ingredients of SINGULAIR SPRINKLES.
- is under the age of 2 years.

Take special care with SINGULAIR SPRINKLES

- Give your child SINGULAIR SPRINKLES every day for as long as your doctor prescribes it, even if your child has no asthma symptoms.
- Do not give your child SINGULAIR SPRINKLES for the immediate relief of an asthma attack. If your child gets an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.
- Always have your child's inhaled rescue medicine for asthma attacks with you.
- If your child's asthma symptoms get worse, or if you need to increase the use of your child's inhaled rescue medicine for asthma attacks, call your doctor right away.
- Do not stop giving or lower the dose of your child's other asthma medicines unless your doctor tells you to.
- If your doctor has prescribed a medicine for your child to use before exercise, keep using that medicine unless your doctor tells you not to.
- If your child's asthma is known to be made worse by aspirin, do not use aspirin and other non-steroidal anti-inflammatory drugs.

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

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

Use in children

SINGULAIR SPRINKLES is for children 2 to 5 years old.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding 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 breastfeeding women has not been established. SINGULAIR SPRINKLES has not been studied in pregnant women.

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

Driving and using machinery

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

Taking other medicines with SINGULAIR SPRINKLES

In general, SINGULAIR SPRINKLES does not interfere with other medicines that your child may be taking. However, some medicines may affect how SINGULAIR SPRINKLES works, or SINGULAIR SPRINKLES may affect how your child's other medicines work. It is important to tell your doctor about all drugs that your child is using or plans 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 SPRINKLES with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

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

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

Your child should take SINGULAIR SPRINKLES once a day with or without food, as your doctor has prescribed. The dose for children 2 to 5 years old is one packet of 4 mg oral granules daily in the evening.

APPROVED: 3 JUNE 2011

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

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

How should I give SINGULAIR SPRINKLES to my child?

Do not open the packet until ready to use.

SINGULAIR SPRINKLES can be given:

- directly in the mouth
- mixed with a spoonful of cold or room temperature soft food (for example, applesauce).
- Mix all of the contents of SINGULAIR SPRINKLES into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.
- Be sure the child is given the entire spoonful of the oral granules mixed with food, immediately (within 15 minutes). **IMPORTANT:** Never store any oral granules mixed with food for use at a later time.

SINGULAIR SPRINKLES are not intended to be dissolved in liquid. However, your child may take liquids after swallowing SINGULAIR SPRINKLES.

Do not share medicines prescribed for you with others.

If your child takes more SINGULAIR SPRINKLES than he/she should

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

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

If your child forgets to take SINGULAIR SPRINKLES

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

SINGULAIR SPRINKLES	APPROVED PIL
APPROVED: 3 JUNE 2011	

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)	Paediatric Patients 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	

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.

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 system 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 bleed

APPROVED: 3 JUNE 2011

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

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

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

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

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 SPRINKLES?

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

STORING AND DISPOSING OF SINGULAIR SPRINKLES

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 SPRINKLES?

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

The packet should not be opened until ready to use. The full dose must be administered immediately (within 15 minutes). If mixed with food, it must not be stored for future use.

Store all medicines out of reach and sight of children.

PRESENTATION OF SINGULAIR SPRINKLES

SINGULAIR SPRINKLES (500 mg net weight) is available in foil packets in pack sizes of 28 or 30 packets per carton.

IDENTIFICATION OF SINGULAIR SPRINKLES

SINGULAIR SPRINKLES: White, granular, coarse, free-flowing homogenous solid, with no extraneous particles present.

SINGULAIR SPRINKLES	APPROVED PIL
APPROVED: 3 JUNE 2011	

REGISTRATION NUMBER

SINGULAIR SPRINKLES: A38/10.2.2/0584

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

MSD (Pty) Ltd
16th Road
Halfway House
1685
Telephone number: 011 655 3000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

3 JUNE 2011

(WPPI-SGA-MF-072008)