PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SINGULAIR® 10 mg Film-coated Tablets

SINGULAIR® 5 mg Chewable Tablets

SINGULAIR® 4 mg Chewable Tablets

SINGULAIR® SPRINKLES

montelukast sodium

Contains sugar:

SINGULAIR 10 mg Film-coated Tablets contain lactose

SINGULAIR 5 mg Chewable Tablets contain mannitol and aspartame

SINGULAIR 4 mg Chewable Tablets contain mannitol and aspartame

SINGULAIR SPRINKLES contain mannitol

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, pharmacist, nurse or other healthcare provider.
- SINGULAIR 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.

What is in this leaflet

1. What SINGULAIR is and what it is used for

2. What you need to know before you take SINGULAIR

3. How to take SINGULAIR

4. Possible side effects

5. How to store SINGULAIR

6. Contents of the pack and other information

1. What SINGULAIR is and what it is used for

SINGULAIR is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

SINGULAIR 10 mg Film-coated Tablets are indicated in adults and children 15 years of age and older for the prevention and treatment of asthma.
In adult patients, in whom SINGULAIR is used for asthma, SINGULAIR may provide some symptomatic relief of seasonal allergic rhinitis (hayfever).

SINGULAIR 5 mg Chewable Tablets are indicated in paediatric patients over 6 years of age for the prevention and treatment of asthma.

SINGULAIR 4mg Chewable Tablets and SPRINKLES are indicated in paediatric patients 2 to 5 years of age for the prevention and treatment of asthma.

2. What you need to know before you take SINGULAIR:

Do not take, or give your child SINGULAIR:

- If he/she/you are allergic to montelukast or to any of the other ingredients of SINGULAIR.

Do not give your child SINGULAIR 10 mg Film-coated Tablets:

- if he/she is below the age of 15 years as safety and efficacy have not been demonstrated.

Do not give your child SINGULAIR 5 mg Chewable Tablets:

- if he/she is below the age of 6 years, as safety and efficacy have not been demonstrated.

Do not give your child SINGULAIR 4 mg Chewable Tablets and SPRINKLES to take:

- if he/she is below the age of 2 years, as safety and efficacy have not been demonstrated.

Warnings and precautions

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 asthma symptoms or if you or your child has an asthma attack.
- Do not take or give your child SINGULAIR for the immediate relief of an asthma attack. If you or your child gets an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.
- Always have your or your child's inhaled rescue medicine for asthma attacks with you.
- If you or your child's asthma symptoms get worse or more frequent, or if you or your child needs to use more of you or your child's inhaled rescue medicine for asthma attacks, you should contact your doctor immediately.
- Do not stop giving or lower the dose of you or your child's other asthma medicines unless your doctor tells you to.
- If your doctor has prescribed a medicine to use before exercise, that medicine should be continued to be used unless the doctor recommends stopping.

- It is important that you or your child take all asthma medicines prescribed by your doctor. SINGULAIR should not be replaced with other asthma medicines your doctor has prescribed.
- If you or your child's asthma is known to be made worse by aspirin, aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen should not be taken.
- If you or your child develops a combination of symptoms such as flu-like illness, pins and needles or numbness of your arms or legs, worsening of lung symptoms and/or rash, tell your doctor immediately.
- Behaviour and mood-related changes have been reported in patients taking SINGULAIR. Tell your doctor if you or your child experiences these changes while taking SINGULAIR (see Possible Side Effects).

Children

SINGULAIR 5 mg Chewable Tablets are for children 6 to 14 years of age.

SINGULAIR 4 mg Chewable Tablets and SPRINKLES are for children 2 to 5 years of age.

Other medicines and SINGULAIR

Always tell your healthcare provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

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, including those obtained without a prescription.

SINGULAIR with food and drink

SINGULAIR can be taken with or without food.

Pregnancy and Breastfeeding

The safety of SINGULAIR in pregnant and breastfeeding women has not been established.

Pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking SINGULAIR.

Breastfeeding

It is not known if SINGULAIR is excreted in human milk. Therefore, SINGULAIR should not be used if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine

Driving and using machines

SINGULAIR may cause side effects, such as drowsiness and dizziness, which may affect your ability to drive or operate machines.

SINGULAIR 10 mg Film-coated Tablets contain lactose and SINGULAIR 4 and 5 mg Chewable Tablets contain aspartame

SINGULAIR 10 mg Film-coated Tablets contain lactose. If you or your child have the rare hereditary condition of lactose intolerance, you or your child should not take SINGULAIR. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

If you or your child has phenylketonuria, you should note that SINGULAIR 5 mg and 4 mg chewable tablets contain aspartame, which is a source of phenylalanine. It may be harmful to patients with phenylketonuria as it contains aspartame.

3. How to take SINGULAIR

Always take SINGULAIR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You or your child should take SINGULAIR once a day in the evening with or without food, as the doctor has prescribed.

SINGULAIR 10 mg Film-coated Tablets:

The dose for adults and adolescents 15 years of age and older for treatment of asthma is one 10 mg tablet each evening.

SINGULAIR 5 mg Chewable Tablets:

The dose for children 6 to 14 years of age for the treatment of asthma is one 5 mg chewable tablet each evening. SINGULAIR 5 mg Chewable Tablets have not been studied in seasonal hay fever 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.

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 or your child with any other person.

SINGULAIR 4 mg Chewable Tablets:

The dose for children 2 to 5 years of age for the treatment of asthma is one 4 mg chewable tablet each evening.

SINGULAIR SPRINKLES:

The dose for children 2 to 5 years of age is one whole packet of SPRINKLES each evening.

Do not open a packet until you are ready to use it.

SINGULAIR SPRINKLES can be given:

- directly into the mouth or
- by mixing one whole packet with a spoonful of cold or room temperature soft food (for example, apple sauce).

Give all this food mixture immediately (within 15 minutes).

IMPORTANT: Never store any of this mixture 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.

If you or your child took more SINGULAIR than you/she/he 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, irritability, restlessness and tremor.

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 each evening.

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

4. Possible side effects

SINGULAIR can have side effects.

Not all side effects reported for SINGULAIR are included in this leaflet. Should your general health worsen while taking SINGULAIR, or if you experience any untoward effects while taking SINGULAIR, please consult your healthcare provider for advice.

If any of the following happens, stop taking SINGULAIR and tell your doctor immediately or go to the casualty department at your nearest hospital, if you or your child:

- develops a combination of symptoms such as flu-like illness, pins and needles or numbness of your arms or legs, worsening of lung symptoms and/or rash, as it may be an increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis)
- develops allergic reactions, including sudden life-threatening allergic reactions, such as swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, hives, itching, rash, bruising
- develops hepatitis (symptoms may include fatigue, abdominal discomfort, nausea or yellowing of the skin or whites of the eyes).

These are all very serious side effects. If you or your child has them, this may be a serious reaction to SINGULAIR that may need urgent medical attention or hospitalisation.

If any of the following happens, stop taking SINGULAIR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- thoughts and attempted actions of suicide
- seizure (fits)

Tell your doctor immediately if you notice any behaviour and mood-related changes that have been reported with the use of SINGULAIR:

- abnormal dreams
- seeing, feeling or hearing things that are not there (hallucinations)
- agitation, including aggressive behaviour
- depression
- disturbance in attention
- memory impairment
- obsessive-compulsive symptoms
- feeling anxious
- inability to sleep
- irritability, restlessness
- tremor (shaking or trembling)
- uncontrolled muscle movements (tic)
- hostility
- disorientation
- sleep walking
- stuttering

Tell your doctor if you notice any of these side effects reported with use of SINGULAIR:

- increased bleeding tendency (low blood platelet count)
- palpitations
- dizziness, drowsiness, pins and needles/decreased feeling or sensitivity (especially in the skin)
- nosebleed, swelling (inflammation) of the lungs
- diarrhoea, indigestion, nausea, vomiting
- joint pain, aching muscles including muscle cramps
- bedwetting in children

- swelling, fever
- weakness
- tiredness
- upper respiratory infections

Tell your doctor if you notice any of the following side effects frequently reported in clinical studies:

- headache
- thirst
- abdominal pain
- increased liver enzymes, as determined by laboratory tests

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SINGULAIR.

5. How to store SINGULAIR

Do not use SINGULAIR after the month and year following Exp.: on the cartons.

Return all unused medicines to your pharmacist.

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

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

SINGULAIR SPRINKLES: 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.

6. Contents of the pack and other information

What SINGULAIR contains

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

It is available as:

- a 10 mg Film-coated Tablet for adults and adolescents 15 years and older.
- a 5 mg Chewable Tablet for children 6 to 14 years of age
- a 4 mg Chewable Tablet for children 2 to 5 years of age
- a packet of SPRINKLES for children 2 to 5 years of age

Each 10 mg film-coated tablet contains 10 mg of montelukast and each 5 mg chewable tablet contains 5 mg of montelukast.

Each 4mg chewable tablet contains 4mg of montelukast and each packet of SPRINKLES contains 4 mg of montelukast.

In addition, SINGULAIR contains the following inactive ingredients:

SINGULAIR 10 mg Film-coated Tablets contains: carnauba wax, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, methyl hydroxypropyl cellulose, microcrystalline cellulose, red ferric oxide, titanium dioxide, yellow ferric oxide. Contains sugar (lactose monohydrate).

SINGULAIR 5 mg and 4 mg Chewable Tablets contain: artificial cherry flavour, aspartame, croscarmellose sodium, hydroxylpropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, red ferric oxide.
SINGULAIR 5 mg and 4 mg Chewable Tablets contain sugar (mannitol and aspartame).

SINGULAIR SPRINKLES contains**:** hydroxypropyl cellulose, magnesium stearate, mannitol.
SINGULAIR SPRINKLES contains sugar (mannitol).

What SINGULAIR looks like and contents of the pack

SINGULAIR 10 mg Film-coated Tablets: A beige, rounded square film-coated tablet with ‘SINGULAIR’ engraved on one side and ‘MSD 117’ on the other.
SINGULAIR 10 mg Film-coated Tablets are available in OPA/Al/PVC blister packs of 28.

SINGULAIR 5 mg Chewable Tablets: A pink, round, biconvex tablet with ‘SINGULAIR’ engraved on one side and ‘MSD 275’ on the other.
SINGULAIR 5 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 28.

SINGULAIR 4 mg Chewable Tablets: A pink, oval, biconvex tablet with a cherry taste and odour. 'SINGULAIR’ is engraved on one side and ‘MSD 711’ on the other.
SINGULAIR 4 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 28.

SINGULAIR SPRINKLES: White, granular, coarse, free-flowing homogenous solid, with no extraneous particles present.
SINGULAIR SPRINKLES (500 mg net weight) is available in low density polyethylene/aluminium /polyester film foil packets in pack sizes of 28 per carton.

Holder of Certificate of Registration

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