

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SINTRINE ORAL GRANULES

montelukast sodium

contains mannitol (484,70 mg per sachet)

Read all of this leaflet carefully before you start taking SINTRINE ORAL GRANULES

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

1. What SINTRINE ORAL GRANULES is and what it is used for

SINTRINE ORAL GRANULES contains the active substance montelukast and is used in children (2 to 5 years) for the chronic treatment of atopic (allergic) asthma and to prevent asthma symptoms.

How it works:

Montelukast, the active ingredient in SINTRINE ORAL GRANULES is a leukotriene receptor antagonist that blocks substances called leukotrienes.

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

2. What you need to know before you give SINTRINE ORAL GRANULES to your child**Do not give SINTRINE ORAL GRANULES to your child**

- If your child is hypersensitive (allergic) to montelukast or any of the other ingredients of SINTRINE ORAL GRANULES (listed in section 6).
- If your child is younger than 2 years old.

Warnings and precautions

Talk to your doctor or pharmacist before giving SINTRINE ORAL GRANULES to your child:

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- SINTRINE ORAL GRANULES is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's emergency asthma pump or emergency medicine for asthma attacks with you.
- If your child's gets asthma attacks during exercise and your child's doctor has prescribed an emergency asthma pump medicine for your child to use before or during exercise, your child should keep using that medicine.

- It is important that your child take all asthma medications prescribed by his/her doctor.
SINTRINE ORAL GRANULES should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops 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.
- 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 his/her asthma worse.

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If you or your child develop such symptoms while taking montelukast, you should contact your doctor.

Other medicines and SINTRINE ORAL GRANULES

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

Some medicines may affect how SINTRINE ORAL GRANULES works, or SINTRINE ORAL GRANULES may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting SINTRINE ORAL GRANULES:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used to treat high fat levels in your blood).

SINTRINE ORAL GRANULES with food and drink

You can give SINTRINE ORAL GRANULES to your child with or without food. For more information see section 3 on “How to take SINTRINE ORAL GRANULES” below.

Pregnancy and breastfeeding

This subsection is not applicable for SINTRINE ORAL GRANULES since they are intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for the SINTRINE ORAL GRANULES 4 mg granules since they are intended for use in children 2 years to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

SINTRINE ORAL GRANULES 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 SINTRINE ORAL GRANULES may affect some patients' ability to drive or operate machinery.

3. How to take SINTRINE ORAL GRANULES

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

Always have your child take SINTRINE ORAL GRANULES exactly as your doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

- You should give SINTRINE ORAL GRANULES to your child under supervision every evening.
- Keep giving SINTRINE ORAL GRANULES to your child even when your child has no symptoms.

For children 2 to 5 years of age:

The recommended dose is one sachet of SINTRINE ORAL GRANULES to be taken by mouth each evening.

If you are giving SINTRINE ORAL GRANULES to your child, be sure that your child does not take any other products that contain the same active ingredient, montelukast. Check with your doctor, pharmacist or other healthcare provider if you are not sure.

How should I give SINTRINE ORAL GRANULES to my child?

This medicine is for oral use.

- Do not open the sachet until ready to use
- SINTRINE ORAL GRANULES can be given either:
 - directly in the mouth;
 - OR mixed with a spoonful of cold or room temperature soft food (for example, applesauce, ice cream, carrots and rice).
- Mix all of the contents of the SINTRINE ORAL GRANULES 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 granule/food mixture immediately (within 15 minutes).

IMPORTANT: Never store any granule/food mixture for use at a later time.

- SINTRINE ORAL GRANULES is not intended to be dissolved in liquid. However, your child may take liquids after swallowing SINTRINE ORAL GRANULES.
- SINTRINE ORAL GRANULES can be taken without regard to the timing of food intake.

Your doctor will tell you how long your child's treatment with SINTRINE ORAL GRANULES will last.

If you have the impression that the effect of SINTRINE ORAL GRANULES is too strong or too weak, tell your doctor or pharmacist.

If your child takes more SINTRINE ORAL GRANULES than he/she should

In the event of overdosage, consult your doctor, pharmacist or other healthcare provider. If neither is available, contact the nearest hospital or poison control centre and take your child's box of SINTRINE ORAL GRANULES with you.

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 give SINTRINE ORAL GRANULES to your child

Give SINTRINE ORAL GRANULES to your child exactly as your doctor has told you. However, if you forget to give SINTRINE ORAL GRANULES to your child, just give the usual amount of one sachet once daily.

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

If your child stops taking SINTRINE ORAL GRANULES

SINTRINE ORAL GRANULES can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking SINTRINE ORAL GRANULES for as long as your doctor has told you. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

4. Possible side effects

SINTRINE ORAL GRANULES can have side effects.

Not all side effects reported for SINTRINE ORAL GRANULES are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking SINTRINE ORAL GRANULES please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to SINTRINE ORAL GRANULES and may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression, hallucinations, disorientation, suicidal thoughts and actions
- seizure
- increased bleeding tendency
- tremor
- rapid or fast heart beating (palpitations)
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of lung symptoms and/or rash (Churg-Strauss syndrome) (see section 2)
- low blood platelet count (that your doctor will see from a blood test)
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

These are all serious side effects. If your child has them, he/she may need urgent medical attention.

Other side effects while the medicine has been on the market

Frequent:

- upper respiratory infection

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes (that your doctor will see from a blood test)

Less frequent:

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, disturbance in attention, memory impairment, uncontrolled muscle movements, obsessive-compulsive symptoms, stuttering
- 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
- tender red lumps under the skin, most commonly on your shins (erythema nodosum)

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, or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SINTRINE ORAL GRANULES.

Suspected side-effects can also be reported directly to the Holder of Certificate of Registration (HCR) via the website: <https://pvi1j.solutions.iqvia.com> or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store SINTRINE ORAL GRANULES

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.
- The sachets should not be opened until required for use.
- Keep the sachets in the carton until required for use.
- Do not use after the expiry date stated on the sachet / carton.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SINTRINE ORAL GRANULES contains

Each sachet of SINTRINE ORAL GRANULES contains 4.15 mg of montelukast sodium equivalent to 4.00 mg of montelukast.

SINTRINE ORAL GRANULES contains mannitol (484.70mg per sachet).

Excipients: Hydroxypropyl cellulose, mannitol, magnesium stearate.

What SINTRINE ORAL GRANULES looks like and contents of the pack

Oral granules.

White to off white granules.

Pouch laminate sachet (PET/Aluminium foil/PE).

The sachets are packed in an outer cardboard carton.

Packs sizes of 7, 10, 14, 20, 28, 30 and 100 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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2090

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