

PATIENT INFORMATION LEAFLET

SINTAIR RANGE

SCHEDULING STATUS

S3

SINTAIR 4 mg chewable tablets

SINTAIR 5 mg chewable tablets

SINTAIR 10 mg tablet

Montelukast sodium

SINTAIR contains a sugar alcohol called mannitol [SINTAIR 4 mg (75 mg), SINTAIR 5 mg (94 mg) and SINTAIR 10 mg (188 mg)].

SINTAIR contains a sweetener called aspartame [SINTAIR 4 mg (0,300 mg), SINTAIR 5 mg (0,375 mg), SINTAIR 10 mg (0,750 mg)].

Read all of this leaflet carefully before you start taking SINTAIR

- 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.
- SINTAIR 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 SINTAIR is and what it is used for
2. What you need to know before you take SINTAIR
3. How to take SINTAIR
4. Possible side effects

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5. How to store SINTAIR
6. Contents of the pack and other information

1. What SINTAIR is and what it is used for

SINTAIR is used to prevent and treat asthma.

- SINTAIR 4 mg chewable tablets are used in children from 2 to 5 years of age.
- SINTAIR 5 mg chewable tablets are used in children from 6 years of age.
- SINTAIR 10 mg tablets are used in adults and children from 15 years of age.

SINTAIR used in asthmatic adults can also provide relief of seasonal allergic rhinitis (hay fever).

2. What you need to know before you take SINTAIR

Do not take SINTAIR:

- if you are hypersensitive (allergic) to montelukast, or to any of the ingredients of SINTAIR (see section 6)
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

If you are the parent or caregiver of a child, do not give:

- SINTAIR 4 mg to children younger than 2 years, as its safety has not been established in this age group.
- SINTAIR 5 mg to children younger than 6 years, as its safety has not been established in this age group.
- SINTAIR 10 mg to children younger than 15 years, as its safety has not been

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established in this age group.

Warnings and precautions

Take special care with SINTAIR:

- SINTAIR will not reverse the sudden narrowing and tightness of your airways during an acute asthma attack, including status asthmaticus (a medical emergency that requires immediate medical attention). If you experience an acute asthma attack, you can continue to take SINTAIR.
- You should seek medical attention if you or your child develop a skin rash or skin lesions (abnormal growths or appearance of the skin), experience worsening of your asthma symptoms or have a feeling of numbness, weakness or tingling in your hands and feet.
- You should inform your doctor if you or your child start feeling agitated, aggressive, hostile, anxious, have abnormal dreams, start seeing and hearing things, feel depressed, cannot sleep, are irritable and restless, start thinking about harming yourself, including having suicidal ideas and experience tremors, after starting SINTAIR treatment.
- If you are aware that you or your child is sensitive to aspirin and other non-steroidal anti-inflammatory medicines, such as ibuprofen, you should continue to avoid these medicines during treatment with SINTAIR.
- SINTAIR is not for the treatment of an acute attack of asthma. You or your child should have appropriate inhalation medication available to treat worsening of asthma. If an acute attack occurs, you or your child should follow the instructions your doctor has given you for that situation. Therapy with SINTAIR does not need to be stopped during an acute attack.

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- If you or your child have liver problems, tell your doctor.
- It is important that you or your child take SINTAIR daily as prescribed, even when you have no symptoms or your symptoms are well controlled, as well as during periods of worsening asthma.
- You should contact your doctor immediately if you or your child's asthma is not well controlled or if you or your child requires inhalation therapy more often than usual in a 24-hour period.
- You or your child should not use SINTAIR alone for the management and treatment of a tight chest caused by exercise.
- If you or your child's asthma worsens during exercise, you should continue with your usual inhaled medicine to prevent such occurrences. Your doctor will prescribe additional inhaled medicine for immediate rescue therapy when an asthma attack occurs during or after exercise.
- If you or your child is also using inhaled or oral corticosteroids, you should never suddenly stop using that and replace it with SINTAIR therapy. Your doctor will advise how to gradually stop using the corticosteroids and when to introduce SINTAIR therapy.
- You or your child should not decrease the dose or stop using SINTAIR unless instructed by your doctor.
- If you have porphyria (a rare hereditary disease affecting the blood pigment with symptoms such as dark urine and extreme sensitivity of the skin to light).

Other medicines and SINTAIR

Always tell your healthcare provider if you are taking any other medicine. (This includes

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complementary or traditional medicines.)

- SINTAIR may routinely be used together with other medicines which are used in the prevention and treatment of chronic asthma.
- SINTAIR does not significantly change the activity of medicines such as theophylline (used to treat asthma, a tight chest, infection of the lungs and lung ducts and emphysema), warfarin (used as a blood-thinning medicine), digoxin (used to treat heart conditions), fexofenadine (used to treat allergies), oral contraceptives and corticosteroids such as prednisone or prednisolone (used to treat general inflammatory reactions in the body).
- Your doctor will monitor your treatment if you should use SINTAIR together with phenobarbitone (a medicine used to make you relax), phenytoin (used in epilepsy to prevent fits), rifampicin (used for the treatment of tuberculosis), or ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- SINTAIR does not significantly change the activity of medicines such as rosiglitazone and repaglinide (used to control high blood sugar in patients with type 2 diabetes) and paclitaxel (used in the treatment of certain cancers).
- Use of SINTAIR with gemfibrozil (used to treat high cholesterol) does not require any dosage adjustment, but an increase in adverse reactions may result and your doctor will monitor your treatment.
- Interactions with concurrent use of SINTAIR and trimethoprim (used to treat bacterial infections) are not expected.

SINTAIR with food and drink

SINTAIR can be taken with or without food.

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Pregnancy, breastfeeding and fertility

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 professional for advice before using SINTAIR.

DO NOT take SINTAIR if you are pregnant or planning to become pregnant (see Do not take SINTAIR).

Driving and using machines

SINTAIR may cause dizziness and drowsiness which may affect your ability to drive and use machinery. You are therefore advised not to drive or use machinery while taking SINTAIR.

It is not always possible to predict to what extent SINTAIR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SINTAIR affects them.

SINTAIR contains aspartame

SINTAIR contains aspartame, a source of phenylalanine, which may be harmful to people with phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take SINTAIR

Do not share medicines prescribed for you with any other person. Always take SINTAIR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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The recommended dosage of SINTAIR is once a day in the evening with or without food as prescribed by your doctor.

Your doctor will decide on the dosage depending on your condition.

For the treatment of asthma, the usual dosages are:

- Children from 2 to 5 years old: one SINTAIR 4 mg chewable tablet daily.
- Children from 6 to 14 years old: one SINTAIR 5 mg chewable tablet daily.
- Adults and children from 15 years and older: one SINTAIR 10 mg tablet daily.

The same dosage is used in patients who receive SINTAIR to use together with additional asthma medicine.

For the treatment of patients with both asthma and allergic rhinitis the usual dose is:

- adults and children from 15 years and older: one SINTAIR 10 mg tablet daily.

Your doctor will tell you how long your treatment with SINTAIR will last. Do not stop treatment early because it is important to continue taking SINTAIR for as long as your doctor prescribes it, in order to maintain control of your or your child's asthma.

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

If you take more SINTAIR than you should

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

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Symptoms of overdose may include:

- headache, vomiting, stomach pain, excessive (abnormal) movement, dilation of the pupil of the eyes, inability to sleep, and thirst.

If you forget to take SINTAIR

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for the missed dose.

4. Possible side effects

SINTAIR can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINTAIR. You may need urgent medical attention or hospitalisation.

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

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- chest pain
- porphyria (severe stomach pain, pain in your back and legs)
- palpitations (fast irregular heartbeat)
- thinking of killing yourself (suicidal ideation) and suicidal behaviour
- feeling confused, disorientated, nervous or restless
- having hallucinations (strange visions or sounds)
- yellowing of the skin and eyes, clay-coloured stools, dark urine, breath odour - an indication of liver disease
- inflammation of the liver (hepatitis), with symptoms such as fatigue, loss of appetite and muscle or joint ache
- seizures (fits)
- pancreatitis with symptoms such as nausea, vomiting, swollen stomach.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abnormal blood test results
- upper respiratory tract infections (bronchitis, coughing)
- nasal congestion (stuffy nose), influenza, cough
- gastroenteritis, diarrhoea, constipation, abdominal pain, bloating
- vertigo (feeling unbalanced/spinning head)
- indigestion, thirst
- nausea, vomiting
- headache, dizziness

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- skin rashes
- swelling in any part of the body, fever.

Less frequent side effects:

- abnormal dreams, insomnia (sleeplessness), sleep-walking
- feeling weak or tired
- feeling irritable, aggressive, anxious or depressed, restless, problems concentrating, memory loss, disorientation, nervousness
- hyperventilate (panic attack), shortness of breath
- pus in the urine
- increased bleeding or nose bleeds
- muscle or joint pain, muscle weakness, stiffness or cramps
- drowsiness
- feeling dizzy or shaky (tremors)
- sensations of tingling, burning, pricking (pins and needles), or numbness
- experiencing sensations of reduced sense of touch
- skin conditions such as itchy, scaly red or abnormal redness of the skin, unusual bruising or bleeding
- unusual tiredness or weakness and experiencing stress (trauma).

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

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SINTAIR.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store SINTAIR

Store all medicines out of reach of children.

- Store at or below 25 °C
- Keep in outer carton until required for use.
- Protect from moisture and light.

Do not use after the expiry date stated on the carton.

Return all unused medicine 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 SINTAIR contains:

SINTAIR 4 mg: The active substance in each chewable tablet is montelukast sodium, equivalent to 4 mg montelukast.

SINTAIR 5 mg: The active substance in each chewable tablet is montelukast sodium, equivalent to 5 mg montelukast.

SINTAIR 10 mg: The active substance in each tablet is montelukast sodium, equivalent to 10 mg montelukast.

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The other ingredients are:

SINTAIR 4 mg and SINTAIR 5 mg: Aspartame (sweetener), cherry flavour, croscarmellose sodium, ferric oxide red (colourant), magnesium stearate, mannitol and microcrystalline cellulose.

SINTAIR 10 mg: Aspartame (sweetener), cherry flavour, croscarmellose sodium, ferric oxide red (colourant), ferric oxide yellow (colourant), magnesium stearate, mannitol and microcrystalline cellulose.

What SINTAIR looks like and contents of the pack

SINTAIR 4 mg: Pink coloured, oval biconvex shaped, uncoated tablets, with a break-line on both sides.

SINTAIR 5 mg: Pink coloured, round shaped, uncoated tablets, with a break-line on both sides.

SINTAIR 10 mg: Light brown coloured, round biconvex shaped, uncoated tablets, with a break-line on both sides.

Aluminium/Aluminium blisters of 10 tablets each. Each carton contains three strips of tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

17 August 2022

Registration numbers

SINTAIR 4 mg: A44/10.2.2/0829

SINTAIR 5 mg: A44/10.2.2/0830

SINTAIR 10 mg: A44/10.2.2/0831

NAMIBIA:

Sintair 4 mg: NAM NS2 13/10.2.2/0214

Sintair 5 mg: NAM NS2 13/10.2.2/0215

Sintair 10 mg: NAM NS2 13/10.2.2/0216