SINTAIR

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE
SINTAIR 4 mg chewable tablets
SINTAIR 5 mg chewable tablets
SINTAIR 10 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
SINTAIR 4 mg: Each chewable tablet contains montelukast sodium, equivalent to montelukast 4 mg.
SINTAIR 5 mg: Each chewable tablet contains montelukast sodium, equivalent to montelukast 5 mg.
SINTAIR 10 mg: Each tablet contains montelukast sodium, equivalent to montelukast 10 mg.

SINTAIR tablets contain a form of sugar (mannitol).
For each strength of tablet, the quantity of mannitol is: SINTAIR 4 mg (75 mg), SINTAIR 5 mg (94 mg) and SINTAIR 10 mg (188 mg).

SINTAIR tablets contain sweetener (aspartame). For each strength of tablet the quantity of aspartame is: SINTAIR 4 mg (0,300 mg), SINTAIR 5 mg (0,375 mg) and SINTAIR 10 mg (0,750 mg).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
4 mg and 5 mg chewable tablets.
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.

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

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- SINTAIR 4 mg chewable tablets are indicated in paediatric patients 2 - 5 years of age for the prophylaxis and chronic treatment of atopic asthma
- SINTAIR 5 mg chewable tablets are indicated in paediatric patients from 6 years of age for the prophylaxis and chronic treatment of atopic asthma
- SINTAIR 10 mg tablets are indicated in adults and children 15 years of age and older for the prophylaxis and chronic treatment of atopic asthma
- in asthmatic adults in whom SINTAIR is indicated, SINTAIR may provide some symptomatic relief of seasonal allergic rhinitis.

4.2 Posology and method of administration
Posology
- SINTAIR 4 mg/5 mg are chewable tablets
- SINTAIR should be taken once daily in the evening
- SINTAIR tablets may be taken with or without food
- patients should be advised to continue taking SINTAIR while their asthma is controlled, as well as during periods of worsening asthma.

Treatment for atopic asthma:
Paediatric patients 2 - 5 years: One SINTAIR 4 mg chewable tablet daily.
Paediatric patients 6 - 14 years: One SINTAIR 5 mg chewable tablet daily.
Adults and children 15 years of age and older: One SINTAIR 10 mg tablet daily.

Treatment of patients with both atopic asthma and seasonal allergic rhinitis:
Adults and children 15 years of age and older: One SINTAIR 10 mg tablet, daily. In chronic asthma the dose is given in the evening.
SINTAIR has not been studied in children with both of these conditions.

Treatment for asthma:
SINTAIR can be added to a patient's existing treatment regimen.

Reduction in concomitant therapy:
Bronchodilator treatments: In those patients who are not adequately controlled on bronchodilator alone, SINTAIR can be added to the treatment regimen.
When a clinical response is evident (usually after the first dose), the patient's bronchodilator therapy may be reduced as tolerated.

Inhaled corticosteroids: A reduction in the corticosteroid dose can be made as tolerated.
The dose should be reduced gradually with medical supervision. SINTAIR should not be abruptly substituted for inhaled corticosteroids.

Special populations
No dosage adjustment is necessary for paediatric patients, the elderly, patients with renal insufficiency, patients with mild to moderate hepatic impairment, or for patients of either gender.

Missed dose
Medical practitioners should advise patients who forget to take SINTAIR to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

Method of administration
Oral use.

4.3 Contraindications
SINTAIR is contraindicated in:
- hypersensitivity to montelukast or to any of the ingredients of SINTAIR (see section 6.1)
- pregnancy and lactation (see section 4.6)
- SINTAIR 4 mg: safety and efficacy have not been established in children under the age of 2 years
- SINTAIR 5 mg: safety and efficacy have not been established in children under the age of 6 years
- SINTAIR 10 mg: safety and efficacy have not been established in children under the age of 15 years.

4.4 Special warnings and precautions for use
SINTAIR is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. The efficacy of SINTAIR has not been established for the treatment of acute asthma attacks. Patients should be advised to have appropriate rescue medication available. During acute exacerbations of asthma, therapy with SINTAIR can be continued.

Eosinophilic conditions:
Patients on therapy with SINTAIR may present with eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These events have been associated with the reduction of oral corticosteroid therapy. Medical practitioners should be on the alert for patients presenting with eosinophilia, vasculitic rash, worsening of pulmonary symptoms, cardiac complications, and/or neuropathy. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.

Neuropsychiatric events:
Neuropsychiatric events have been reported in some patients taking SINTAIR. These include agitation, aggression, anxiousness, hostility, dream abnormalities, hallucinations, depression, disorientation, disturbance in attention, memory impairment, somnambulism, insomnia, irritability, restlessness, suicidal ideation and behaviour (including suicide), tic and tremor. Patients and healthcare professionals should be aware of the potential for neuropsychiatric events. Patients should be instructed to inform their healthcare professionals if these events occur as the symptoms may be serious and continue if the treatment is not withdrawn. Therefore, if neuropsychiatric symptoms occur during treatment, SINTAIR should be discontinued.

Hypersensitivity to aspirin:
Patients with a known hypersensitivity to aspirin should continue avoiding aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) while taking SINTAIR. Although SINTAIR is effective in improving airway function in asthmatics, it has not been shown to reduce the bronchoconstrictor response to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs) in aspirin-sensitive asthmatic patients.

Hepatic function impairment:
The metabolism of montelukast may be decreased in patients with mild to moderate hepatic function impairment and clinical evidence of cirrhosis. The half-life may be slightly prolonged; however, dosage adjustment is not necessary. Data are not available in patients with severe hepatic impairment.

Patients should be advised to take SINTAIR daily as prescribed, even if they are asymptomatic, as well as during periods of worsening of asthma, and to contact their medical practitioners if their asthma is not well controlled. Medical attention should be sought if more than the prescribed maximum number of inhalations of short-acting bronchodilator treatment for a 24-hour period is needed.

SINTAIR should not be used as mono-therapy for the management and treatment of exercise-induced bronchospasm. Patients should continue with their usual inhaled beta agonists as prophylaxis and have a short-acting inhaled beta agonist available for rescue, if they experience exacerbations of asthma after exercise.

SINTAIR should not be substituted abruptly for inhaled or oral corticosteroids. The dose of the corticosteroid may be tapered gradually under medical supervision. To ensure safe and appropriate use, patients should be advised to read the patient information leaflet.

Porphyria:
SINTAIR is considered to be unsafe in patients with porphyria because montelukast is considered to be probably porphyrinogenic.

SINTAIR contains aspartame:
SINTAIR tablets contain aspartame as a sweetener, which is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

4.5 Interaction with other medicines and other forms of interaction
SINTAIR may routinely be used together with medicines used in the prophylaxis and chronic treatment of asthma and seasonal allergic rhinitis.

Montelukast, as in SINTAIR, does not significantly change the pharmacokinetics of theophylline, warfarin, digoxin, fexofenadine, oral contraceptives (containing norethindrone 1 mg and ethinyl estradiol 35 µg), prednisone or prednisolone.

Concurrent use of SINTAIR and phenobarbitone results in significant decreases (approximately 40 %) in the area under the curve for montelukast, as a result of induction of hepatic metabolism. No dosage adjustment is necessary. However, clinical monitoring is recommended when potent hepatic enzyme inducers (such as ritonavir, phenytoin, phenobarbitone, rifampicin or St John's wort) or potent hepatic enzyme inhibitors (such as ketoconazole, itraconazole or voriconazole) are used with SINTAIR.

In vitro studies have shown that SINTAIR is a potent inhibitor of cytochrome P450 (CYP) 2C8. However, data from an interaction study involving montelukast and rosiglitazone (a probe substrate representative of medicines primarily metabolised by CYP2C8) demonstrated that montelukast did not significantly inhibit CYP2C8 *in vivo*.
Therefore, SINTAIR is not anticipated to alter the metabolism of medicines metabolised by this enzyme (e.g. paclitaxel, rosiglitazone and repaglinide).

In vitro studies have shown that montelukast, as in SINTAIR, is a substrate of CYP2C8, and to a less significant extent, of 2C9, and 3A4. In a medicine-medicine interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP2C8 and 2C9) gemfibrozil increased the systemic exposure of montelukast by 4,4-fold. No routine dosage adjustment of SINTAIR is required upon co-administration with gemfibrozil or other potent inhibitors of CYP 2C8, but the medical practitioner should be aware of the potential for an increase in adverse reactions.

Based on i*n vitro* data, clinically important medicine interactions with less potent inhibitors of CYP 2C8 (e.g. trimethoprim) are not anticipated. Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast, as contained in SINTAIR.

4.6 Fertility, pregnancy and lactation
SINTAIR should not be used during pregnancy or lactation (see section 4.3).

Pregnancy
The safety of SINTAIR in pregnancy has not been established.
Animal studies do not indicate harmful effects with respect to effects on pregnancy or embryonal/foetal development.

Available data from published prospective and retrospective cohort studies with montelukast use in pregnant women evaluating major birth defects have not established a drug-associated risk. Available studies have methodologic limitations, including small sample size, in some cases retrospective data collection, and inconsistent comparator groups.

Breastfeeding
It is not known if montelukast is excreted in human milk. Women taking SINTAIR should not breastfeed their infants.

Fertility
There is no data on fertility with SINTAIR.

4.7 Effects on ability to drive and use machines
SINTAIR may cause side effects such as dizziness or drowsiness, which may affect the ability to drive. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

4.8 Undesirable effects
a. Tabulated list of adverse effects

System organ class	Frequency	Side effects
Infections and infestations	*Frequent*	Upper respiratory infection
Blood and lymphatic system disorders	*Less frequent*	Agranulocytosis, systemic eosinophilia, vasculitis consistent with Churg-Strauss syndrome, porphyria
	Frequency unknown	Increased bleeding tendency*, thrombocytopenia*
Immune system disorders	*Less frequent*	Decreased immune responsiveness, angioedema
	Frequency unknown	Hypersensitivity reactions* including anaphylaxis*
Metabolism and nutrition disorders	*Less frequent*	Pancreatitis, increased appetite
Psychiatric disorders	*Less frequent*	Insomnia, libido decreased
	Frequency unknown	Abnormal dreams*, dysphemia* (stuttering), hallucinations*, agitation* including aggressive behaviour* or hostility*, anxiousness*, depression*, irritability*, restlessness*, disturbance in attention*, memory impairment*, disorientation*, nervousness*, malaise*, somnambulism*, suicidal thinking* and behaviour* (suicidality), tremor*, tic*, obsessive-compulsive symptoms*
Nervous system disorders	*Less frequent*	Headache, hypersomnia, somnolence
	Frequency unknown	Paraesthesia*, hypoesthesia*, drowsiness*, seizure*, dizziness*
Eye disorders	*Less frequent*	Blepharospasm
Ear and labyrinth disorders	*Frequent*	Vertigo
Cardiac disorders	*Less frequent*	Chest pain
	Frequency unknown	Palpitations*
Vascular disorders	*Less frequent*	Hypertension
Respiratory, thoracic and mediastinal disorders	*Frequent*	Congestion (nasal), cough, influenza
	Less frequent	Epistaxis, shortness of breath, hyperventilation, dysphonia, dyspnoea, oropharyngeal pain, postnasal drip, rhinitis allergic
	Frequency unknown	Pulmonary eosinophilia*, Churg-Strauss syndrome*
Gastrointestinal disorders	*Less frequent*	Dyspepsia, gastroenteritis (infectious), pain (dental), diarrhoea, thirst, abdominal pain, nausea, vomiting, dry mouth, bowel movement irregularity, flatulence, salivary hypersecretion
Hepatobiliary disorders	*Frequency unknown*	Elevated hepatic enzymes*; alanine aminotransferase (ALT)* and aspartate aminotransferase (AST)*, hepatitis* (including cholestatic, hepatocellular, and mixed-pattern liver injury)*, hepatic eosinophilic infiltration*
Skin and subcutaneous tissue disorders	*Less frequent*	Acne, night sweats
	Frequency unknown	Pruritus*, urticaria*, bruising*, angioedema*, erythema nodosum*, erythema multiforme*, rash*
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Arthralgia, myalgia, muscle cramps (spasm), back pain, muscle weakness, pain in extremity
Renal and urinary disorders	*Less frequent*	Pyuria, enuresis in children
General disorders and administrative site conditions	*Frequency unknown*	Pyrexia*, oedema*, asthenia*, fatigue*
Investigations	*Less frequent*	Alanine aminotransferase increased, aspartate aminotransferase increased, eosinophil count increased, haematocrit decreased, haemoglobin decreased, white blood cell count decreased.

*Post-marketing

b. Description of selected adverse reactions
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 - 14 years of age, the safety profile did not change.

Patients on therapy with SINTAIR may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
There were no adverse experiences reported in the majority of overdosage reports.
The most frequently occurring adverse experiences were consistent with the safety profile of montelukast and included headache, vomiting, abdominal pain, hyperkinesia, mydriasis, somnolence and thirst.

In chronic asthma studies, montelukast has been administered at doses up to 200 mg/day to adult patients for 22 weeks and in short-term studies, up to 900 mg/day to patients for approximately one week without clinically important adverse experiences.

Management of overdose:
No specific information is available on the treatment of overdosage with SINTAIR. It is not known whether montelukast, as in SINTAIR, is dialysable by pertinoneal or haemodialysis.
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Leukotriene receptor antagonists
ATC code: R03DC03
Pharmacological classification: A.10.2.2 Other anti-asthmatics (Leukotriene receptor antagonist).

Mechanism of action
Montelukast is a selective leukotriene receptor antagonist of the cysteinyl leukotriene $CysLT_1$ receptor. The cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4) are products of arachidonic acid metabolism that are released from various cells including mast cells and eosinophils. They bind to cysteinyl leukotriene receptors (CysLT) found in the human airway. All the cysteinyl leukotrienes are potent constrictors of the bronchial smooth muscle. On a molar basis LTD_4 is approximately 1 000 times more potent than histamine as a bronchoconstrictor. The receptor responsible for the bronchoconstrictor effect of leukotrienes is the $CysLT_1$ receptor. Although each of the cysteinyl leukotrienes is an antagonist at the $CysLT_1$ receptor, LTE_4 is less potent than either LCT_4 or LTD_4. Montelukast is a selective, high affinity competitive antagonist of the $CysLT_1$ receptor.

5.2 Pharmacokinetic properties
Absorption:
Montelukast 4 mg:
Montelukast is rapidly absorbed following oral administration. The mean peak plasma concentration (C_{max}) for the 4 mg chewable tablet is achieved 2 hours after administration in paediatric patients 2 - 5 years of age in fasted state. Safety and efficacy were demonstrated in clinical studies where the 4 mg chewable tablet was administered without regard to the timing of food ingestion.

Montelukast 5 mg:
The mean peak plasma concentration (C_{max}), for the 5 mg chewable tablet is achieved 2 hours after administration in adults in the fasted state. The mean oral bioavailability is 73 %. Food does not have a clinically important influence with chronic administration.

Montelukast 10 mg:
The mean peak plasma concentration (C_{max}), for the 10 mg tablet is achieved 3 hours (T_{max}), after administration in adults in the fasted state. The mean oral bioavailability is 64 %. A standard meal does not influence the oral bioavailability and C_{max}.

Distribution:
Binding is more than 99 % to plasma proteins. The steady-state volume of distribution of montelukast averages 8 - 11 litres.

Biotransformation:
Montelukast is extensively metabolised in the liver. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and paediatric patients.

In vitro studies using human liver microsomes indicate that cytochrome P450 3A4 and 2C9 are involved in the metabolism of montelukast. Based on further *in vitro* results in human liver microsomes, therapeutic plasma concentrations of montelukast do not inhibit cytochromes P450, 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6.

Elimination:
Elimination data are not available for children 2 - 5 years of age, however, the plasma clearance of montelukast averages 45 mL/min in healthy adults. Following an oral dose of radio-labelled montelukast, 86 % of the radioactivity was recovered in 5-day faecal collections and less than 0,2 % was recovered in urine. Coupled with estimates of montelukast oral bioavailability, this indicates that montelukast and its metabolites are excreted almost exclusively via the bile. The mean plasma half-life of montelukast ranged from 2,7 - 5,5 hours in healthy young adults. Montelukast pharmacokinetics is nearly linear for oral doses up to 50 mg. No difference in pharmacokinetics was noted between dosing in the morning or in the evening. During once daily dosing there is little accumulation of the parent substance in plasma (approximately 14 %).

Pharmacokinetics in special patient groups
Hepatic insufficiency:
Patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis had evidence of decreased metabolism of montelukast resulting in approximately 41 % higher mean montelukast area under the plasma concentration curve (AUC) following a single 10 mg dose. The elimination of montelukast is slightly prolonged compared with that in healthy subjects (mean half-life, 7,4 hours). No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency. There are no clinical data in patients with severe hepatic insufficiency (Child-Pugh score greater than 9).

Renal insufficiency:
Since montelukast and its metabolites are not excreted in the urine, the pharmacokinetics of montelukast was not evaluated in patients with renal insufficiency. No dosage adjustment is recommended in these patients.

Elderly:
The pharmacokinetic profile and the oral bioavailability of a single 10 mg oral dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
SINTAIR 4 mg and SINTAIR 5 mg:
Aspartame (sweetener)
Cherry flavour
Croscarmellose sodium
Ferric oxide red (colourant)
Magnesium stearate
Mannitol
Microcrystalline cellulose.

SINTAIR 10 mg:
Aspartame (sweetener)
Cherry flavour
Croscarmellose sodium
Ferric oxide red (colourant)
Ferric oxide yellow (colourant)
Magnesium stearate
Mannitol
Microcrystalline cellulose.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at or below 25 °C.
Keep the blisters in the outer carton until required for use. Protect from moisture and light.

6.5 Nature and contents of container
Aluminium/aluminium silver coloured blister strips, packed in an outer carton. Available in a pack size of 30 tablets.

6.6 Special precautions for disposal
No special precautions.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel.: +27 21 707 7000
or 0860-PHARMA (742 762)

8. 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

9. DATE OF FIRST AUTHORISATION
26 October 2012

10. DATE OF REVISION OF THE TEXT
06 August 2025

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SINTAIR 4 mg chewable tablets
SINTAIR 5 mg chewable tablets
SINTAIR 10 mg tablets
Montelukast
SINTAIR contains a form of sugar 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 (0,75 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 or your 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
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 a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs.

Blocking leukotrienes improves asthma symptoms, SINTAIR is used to prevent and treat asthma.
- SINTAIR 4 mg chewable tablets are used in children from 2 - 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 any of the other ingredients of SINTAIR (see section 6)
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).

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 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 immediately 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, or whilst taking SINTAIR
- if you are aware that you or your child is sensitive to aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs), 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
- 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 complementary or traditional medicines.)
- SINTAIR may routinely be used together with other medicines which are used in the prevention and treatment of chronic asthma and seasonal hay fever
- 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), St John's wort (used for depression), 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.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using SINTAIR.

DO NOT use SINTAIR if you are pregnant or planning to become pregnant (see Do not use SINTAIR).
The safety of SINTAIR in pregnancy has not been established.

Driving and using machines
SINTAIR may cause dizziness and drowsiness.
You are therefore advised not to drive or use machinery while taking SINTAIR, until you know how it affects you.
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. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), 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.

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:
The usual dose is:
- children from 2 - 5 years old: one SINTAIR 4 mg chewable tablet daily
- children from 6 - 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 overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 using SINTAIR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using 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
- fainting.

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:
- 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, obsessive-compulsive symptoms
- 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)
- 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)
- 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:
- upper respiratory tract infections (bronchitis, coughing)
- nasal congestion (stuffy nose), influenza, cough.

Less frequent side effects:
- increased appetite
- abnormal blood test results
- gastroenteritis, diarrhoea, constipation, abdominal pain, bloating, flatulence, excessive saliva, dry mouth, indigestion, thirst, nausea, vomiting, dental pain, abnormal bowel movement
- swelling in any part of the body, fever
- insomnia (sleeplessness), libido decreased
- headache, sleepiness, excessive sleepiness
- involuntary twitching, blinking or closure of the eyelids
- high blood pressure
- hyperventilate (panic attack), shortness of breath, increased bleeding or nose bleeds, hoarseness, sore throat, postnasal drip, hay fever
- acne, night sweats
- muscle or joint pain, muscle weakness, stiffness or cramps, back pain, pain in extremities
- pus in the urine, bedwetting in children
- increased liver enzymes, as determined by laboratory tests.

The following side effects have been reported but the frequency for them to occur is not known:
- increased bleeding tendency (low blood platelet count)
- abnormal dreams, sleep-walking, stuttering, feeling irritable, aggressive, hostile, anxious or depressed, restless, problems concentrating, memory loss, disorientation, nervousness, sleepwalking, general feeling of being unwell, feeling dizzy or shaky (tremors), tics
- sensations of tingling, burning, pricking (pins and needles), or numbness, experiencing sensations of reduced sense of touch, dizziness, drowsiness
- skin conditions such as itchy, scaly red or abnormal redness of the skin, unusual bruising or bleeding, skin rashes
- feeling weak or tired, lack of energy, fever, general swelling, fatigue.

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. 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 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 the blisters in the 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 montelukast 4 mg.
SINTAIR 5 mg: The active substance in each chewable tablet is montelukast sodium, equivalent to montelukast 5 mg.
SINTAIR 10 mg: The active substance in each tablet is montelukast sodium, equivalent to montelukast 10 mg.

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 silver coloured blister strips, packed in an outer carton. Available in a pack size of 30 tablets.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

SINTAIR 4 mg koubare tablette
SINTAIR 5 mg koubare tablette
SINTAIR 10 mg tablette
Montelukast
SINTAIR bevat a vorm van suiker wat mannitol genoem word [SINTAIR 4 mg (75 mg), SINTAIR 5 mg (94 mg) en SINTAIR 10 mg (188 mg)].
SINTAIR bevat 'n versoeter wat aspartaam genoem word [SINTAIR 4 mg (0,300 mg), SINTAIR 5 mg (0,375 mg), SINTAIR 10 mg (0,75 mg)].

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om SINTAIR te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- SINTAIR is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad
1. Wat SINTAIR is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u SINTAIR neem
3. Hoe om SINTAIR te neem
4. Moontlike newe-effekte
5. Hoe om SINTAIR te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat SINTAIR is en waarvoor dit gebruik word
SINTAIR is 'n leukotriene reseptorantagonis, wat substanse (leukotriene genoem), blokkeer. Leukotriene veroorsaak vernouing en swelling van die lugweë in u longe.

Blokkade van leukotriene verbeter asma simptome en SINTAIR word gebruik om asma te verhoed en te behandel.
- SINTAIR 4 mg koubare tablette word gebruik vir kinders vanaf 2 - 5 jaar oud
- SINTAIR 5 mg koubare tablette word gebruik vir kinders vanaf die ouderdom van 6 jaar
- SINTAIR 10 mg tablette word gebruik vir volwassenes en kinders vanaf die ouderdom van 15 jaar.

SINTAIR word gebruik vir asmatiese volwassenes en kan ook verligting bied vir seisoenale allergiese rinitis (hooikoors).

2. Wat u nodig het om te weet, voordat u SINTAIR neem
Moet nie SINTAIR neem:
- indien u hipersensitief (allergies) is vir montelukast, of vir enige van die bestanddele van SINTAIR nie (sien afdeling 6)
- indien u swanger is of u baba borsvoed nie (sien Swangerskap en borsvoeding).

Indien u 'n ouer of versorger vir 'n kind is, moet nie:
- SINTAIR 4 mg aan kinders jonger as 2 jaar oud gee nie, aangesien die veiligheid nog nie vasgestel is in hierdie ouderdomsgroep nie
- SINTAIR 5 mg aan kinders jonger as 6 jaar oud gee nie, aangesien die veiligheid nog nie vasgestel is in hierdie ouderdomsgroep nie
- SINTAIR 10 mg aan kinders jonger as 15 jaar oud gee nie, aangesien die veiligheid nog nie vasgestel is in hierdie ouderdomsgroep nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met SINTAIR:
- SINTAIR sal nie skielike vernouing of styfheid in u lugweë tydens 'n akute asma-aanval, insluitend status asthmaticus ('n mediese toestand wat onmiddelike mediese aandag verg), omkeer nie. Indien u 'n akute asma-aanval ervaar, gaan voort om SINTAIR te gebruik
- u moet mediese aandag bekom, indien u of u kind 'n veluitslag, of velletsels (abnormale groeisels of voorkoms van die vel) ontwikkel, verergering van u asma simptome ervaar, of gevoelloosheid, swakheid, of tinteling in u hande en voete ondervind
- u moet u dokter onmiddellik inlig, indien u of u kind onrustig, aggressief, vyandiggesind, of angstig begin voel, abnormale drome het, dinge begin sien en hoor, depressief voel, nie kan slaap nie, prikkelbaar en rusteloos voorkom, daaraan dink om uself te beseer (insluitend selfmoordgedagtes) en tremors ervaar, nadat u met SINTAIR behandeling begin het, of tydens behandeling daarmee
- indien u bewus is dat u of u kind sensitief is vir aspirien en ander niesteroïedale anti-inflammatoriese middels (NSAIDs), soos ibuprofen, moet u hierdie medisyne aanhou vermy, tydens behandeling met SINTAIR
- SINTAIR word nie aanbeveel vir die behandeling van 'n akute asma-aanval nie. U of u kind moet gepaste inhalasiemedikasie byderhand hê, om die verergering van asma te behandel. Indien 'n akute aanval voorkom, moet u of u kind, die instruksies soos deur u dokter aanbeveel word in so 'n situasie, volg. Dit is nie nodig om behandeling met SINTAIR te staak tydens 'n akute aanval nie
- indien u of u kind lewerprobleme het, vertel u dokter
- dit is belangrik dat u of u kind SINTAIR daagliks neem, soos voorgeskryf, selfs wanneer u geen simptome het, of u simptome goed onder beheer is, sowel as tydens tydperke waar u asma vererger
- u moet u dokter onmiddellik raadpleeg indien u of u kind se asma nie goed onder beheer is nie, of indien u of u kind inhalasieterapie meer dikwels as normaal in 'n 24-uur tydperk, benodig
- u of u kind moet nie SINTAIR alleen vir die beheer en behandeling van 'n toe bors wat deur oefening veroorsaak word, gebruik nie
- indien u of u kind se asma vererger tydens oefening, moet u aanhou met u gewone inhalasiemedisyne, om sulke omstandighede te verhoed. U dokter sal bykomende inhalasiemedikasie vir onmiddellike reddingsterapie voorskryf, wanneer 'n asma-aanval tydens, of na oefening voorkom
- indien u of u kind ook inasemings- of mondelikse kortikosteroïede gebruik, moet u dit nooit skielik staak en vervang met SINTAIR behandeling nie. U dokter sal aandui hoe om geleidelik die gebruik van kortikosteroïede te staak en wanneer om SINTAIR behandeling te begin
- u of u kind moet nie die dosis verlaag of die gebruik van SINTAIR staak, tensy die dokter so aanbeveel nie
- indien u porfirie het ('n skaars oorerflike siekte, wat die bloedpigment aantas, met simptome soos donker urine en uiterste sensitiwiteit van die vel vir lig).

Ander medisyne en SINTAIR
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende of tradisionele medisyne in).
- SINTAIR mag gereeld saam met ander medisyne wat gebruik word vir die voorkoming en behandeling van chroniese asma, geneem word
- SINTAIR verander nie die werking van medisyne soos teofillien (gebruik om asma, 'n toe bors, infeksie van die longe en longbuise en emfiseem, te behandel), warfarien (gebruik as bloedverdunningmedisyne), digoksien (gebruik om harttoestande te behandel), feksofenadien (gebruik om allergieë te behandel), mondelikse voorbehoedmiddels en kortikosteroïede soos prednisoon of prednisoloon (gebruik om algemene inflammatoriese reaksies in die liggaam te behandel), beduidend nie
- u dokter sal u behandeling monitor, indien u SINTAIR saam met fenobarbitoon ('n medisyne wat gebruik word om u te laat ontspan), Johanneskruid (gebruik vir depressie), fenitoïen (gebruik tydens epilepsie en om aanvalle te verhoed), rifampisien (gebruik vir die behandeling van tuberkulose), of ketokonasool, itrakonasool, of vorikonasool (gebruik om swaminfeksies te behandel), sou gebruik
- SINTAIR verander nie die werking van medisyne soos rosiglitasoon en repaglinied (gebruik vir die beheer van hoë bloedsuiker by pasiënte met tipe 2 diabetes) en paklitaksel (gebruik vir die behandeling van sekere kankers), beduidend nie
- die gebruik van SINTAIR saam met gemfibrosil (gebruik om hoë cholesterol te behandel), benodig nie enige dosisaanpassing nie, maar 'n toename in ongunstige effekte mag voorkom. U dokter sal u behandeling monitor
- interaksies met die gelyktydige gebruik van SINTAIR en trimetoprim (gebruik om bakteriële infeksies te behandel), word nie verwag nie.

SINTAIR saam met kos en drinkgoed
SINTAIR kan saam met, of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of u baba borsvoed, vermoed dat u swanger mag wees, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies, voordat u SINTAIR gebruik.

MOET NIE SINTAIR gebruik indien u swanger is, of beplan om swanger te raak nie (sien Moet nie SINTAIR gebruik). Die veiligheid van SINTAIR tydens swangerskap is nog nie vasgestel nie.

Bestuur en die hantering van masjiene
SINTAIR mag duiseligheid en lomerigheid veroorsaak. U word dus aanbeveel om nie te bestuur, of masjinerie te hanteer, terwyl u SINTAIR gebruik, totdat u weet hoe dit u aantas nie.
Dit is nie altyd moontlik om te voorspel tot watter mate SINTAIR met die daaglikse aktiwiteite van 'n pasiënt inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle weet hoe SINTAIR hulle beïnvloed nie.

SINTAIR bevat aspartaam
SINTAIR bevat aspartaam. Aspartaam is 'n bron van fenielalanien. Dit kan skadelik wees as u fenielketonurie (PKU) het, 'n seldsame genetiese afwyking waarin fenielalanien opbou omdat die liggaam dit nie behoorlik kan verwyder nie.

3. Hoe om SINTAIR te neem
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Neem SINTAIR altyd presies soos deur u dokter aanbeveel word. U moet u dokter of apteker raadpleeg, indien u onseker is.

Die aanbevole dosis SINTAIR is een keer daagliks, in die aand, saam met, of sonder kos, soos deur u dokter voorgeskryf.
U dokter sal op die dosis besluit, in ooreenstemming met u huidige toestand.

Vir die behandeling van asma, is die gewone dosis:
Die gewone dosis is:
- kinders vanaf 2 - 5 jaar oud: een SINTAIR 4 mg koubare tablet daagliks
- kinders vanaf 6 - 14 jaar oud: een SINTAIR 5 mg koubare tablet daagliks
- volwassenes en kinders vanaf 15 jaar oud en ouer: een SINTAIR 10 mg tablet daagliks.

Dieselfde dosering word gebruik deur pasiënte wie SINTAIR ontvang, om saam met bykomende asmamedisyne te gebruik.

Vir die behandeling van pasiënte met beide asma en allergiese rinitis is die gewone dosis:
- volwassenes en kinders vanaf 15 jaar oud en ouer: een SINTAIR 10 mg tablet daagliks.

U dokter sal u vertel vir hoe lank u behandeling met SINTAIR sal duur. Moet nie die behandeling vroegtydig staak nie, want dit is belangrik om SINTAIR aanhoudend te gebruik vir solank as wat u dokter dit voorgeskryf het, om sodoende die beheer van u kind se asma te handhaaf.
Indien u onder die indruk is dat die uitwerking van SINTAIR té sterk, of té swak is, vertel u dokter of apteker.

Indien u meer SINTAIR neem as wat u behoort
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal, of gifbeheersentrum.

Simptome van oordosering mag die volgende insluit:
- hoofpyn, braking, maagpyn, uitermatige (abnormale) beweging, verwyding van die pupil in die oë, onvermoë om te slaap en dors.

Indien u vergeet om SINTAIR te neem
Neem die dosis wat oorgeslaan is, so gou as wat u onthou. Indien dit amper tyd is vir u volgende dosis, slaan die vergete dosis oor en neem die medisyne op die gereelde geskeduleerde tyd. Moet nie 'n dubbeldosis neem om op te maak vir die vergete dosis nie.

4. Moontlike newe-effekte
SINTAIR kan newe-effekte hê.
Nie alle newe-effekte wat vir SINTAIR aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar, terwyl u SINTAIR neem, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van SINTAIR en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, kon u 'n ernstige allergiese reaksie teenoor SINTAIR ondervind het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- borspyn
- porfirie (erge maagpyn, pyn in rug en bene)
- palpitasies (vinnige, onreëlmatige hartklop)
- dink aan selfmoord (selfmoord idees) en selfmoordgedrag
- voel verward, gedisoriënteer, senuweeagtig, of rusteloos, obsessief-kompulsiewe simptome
- hallusineer (vreemde visies of geluide)
- vergeling van die vel en oë, klei-kleurige stoelgang, donker urine, slegte asem – 'n indikasie van lewersiekte
- inflammasie van die lewer (hepatitis), met simptome soos uitputting, aptytverlies en spier- of gewrigspyn
- aanvalle (stuipe)
- 'n kombinasie van simptome soos griep-soortige siekte, spelde en naalde, of gevoelloosheid in u arms of bene, verergering van longsimptome en/of uitslag, aangesien dit tekens van 'n toename in sekere witbloedselle (eosinofille) en moontlike inflammasie van bloedvate regdeur diie liggaam mag wees (sistemise vaskulitis)
- pankreatitis, met simptome soos naarheid, braking, geswelde maag.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter, indien u enige van die volgende opmerk:
Algemene newe-effekte:
- boonste lugweginfeksies (brongitis, hoes)
- neuskongestie (toe neus), griep, hoes.

Minder algemene newe-effekte:
- toename in eetlus
- abnormale bloedtoetsresultate
- gastro-enteritis, diarree, hardlywigheid, buikpyn, voel opgeblase, winderigheid, uitermatige speekselvloei, droë mond, indigestie, dors, naarheid, braking, tandpyn, abnormale dermbeweging
- swelling in enige gedeelte van die liggaam, koors
- insomnie (slaaploosheid), afname in seksdrang
- hoofpyn, slaperigheid, uitermatige slaperigheid
- onwillekeurige spiertrekkings, ooglede wat knip of geslote is
- hoë bloeddruk
- hiperventilasie (paniekaanval), asemnood, toename in bloeding of neusbloeding, heesheid, seer keel, post-nasale drup, hooikoors
- aknee, nagsweet
- spier-, of gewrigspyn, spierswakheid, styfheid of krampe, rugpyn, pyn in die ledemate
- etter in die urine, bednatmaak by kinders
- verhoogde lewerensieme, soos bepaal deur laboratoriumtoetse.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- verhoging in bloedingsneiging (lae bloedplaatjietelling)
- abnormale drome, slaaploop, hakkel, voel prikkelbaar, aggressief, vyandiggesind, angstig, depressief, rusteloos, sukkel om te konsentreer, geheueverlies, disoriëntasie, senuweeagtigheid, algemene gevoel van ongesteldheid, voel duiselig of bewerig (tremors), gewoontespasmas
- tintelende, brandende, prikkelende sensasie (spelde en naalde), of gevoelloosheid, ervaar vermindering in tassensasie, duiseligheid, lomerigheid
- veltoestande soos, jeukerige, skubberige rooi, of abnormale rooiheid van die vel, ongewone kneusing of bloeding, veluitslag
- voel swak of moeg, energieverlies, koors, algemene swelling, uitputting.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.prg), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer ingligting aangaande die veiligheid van SINTAIR in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om SINTAIR te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 °C
Hou die stulpstroke in die buitenste kartonhouer totdat dit benodig word vir gebruik.
Beskerm teen vog en lig.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat SINTAIR bevat:
SINTAIR 4 mg: Die aktiewe bestanddeel in elke koubare tablet is natrium-montelukast, gelykstaande aan montelukast 4 mg.
SINTAIR 5 mg: Die aktiewe bestanddeel in elke koubare tablet is natrium-montelukast, gelykstaande aan montelukast 5 mg.
SINTAIR 10 mg: Die aktiewe bestanddeel in elke tablet is natrium-montelukast, gelykstaande aan montelukast 10 mg.

Die ander bestanddele is
SINTAIR 4 mg en SINTAIR 5 mg: Aspartaam (versoeter), kersiegeursel, kruisgekoppelde natriumkarmellose, magnesiumstearaat, mannitol, mikrokristallyne sellulose en rooi ysteroksied (kleurstof).
SINTAIR 10 mg: Aspartaam (versoeter), geel ysteroksied (kleurstof), kersiegeursel, kruisgekoppelde natriumkarmellose, magnesiumstearaat, mannitol, mikrokristallyne sellulose en rooi ysteroksied (kleurstof).

Hoe SINTAIR lyk en die verpakkingsinhoud
SINTAIR 4 mg: Pienk-kleurige, ovaal, bikonvekse, onbedekte tablette, met 'n breeklyn aan beide kante.
SINTAIR 5 mg: Pienk-kleurige, ronde, onbedekte tablette, met 'n breeklyn aan beide kante.
SINTAIR 10 mg: Ligbruin, ronde, bikonvekse, onbedekte tablette, met 'n breeklyn aan beide kante.
Aluminium/aluminium silwerkleurige stulpstrook, in 'n buitenste kartonhouer. Beskikbaar in verpakkingsgroottes van 30 tablette.

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
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Hierdie inligtingsblad was voorheen hersien
06 Augustus 2025

Registrasienommers
SINTAIR 4 mg: A44/10.2.2/0829
SINTAIR 5 mg: A44/10.2.2/0830
SINTAIR 10 mg: A44/10.2.2/0831

NAMIBIË:
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