

PATIENT INFORMATION LEAFLET – SINTAIR TABLETS:

Please read this leaflet carefully before using SINTAIR 4 mg, 5 mg or 10 mg tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **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.

SCHEDULING STATUS:

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

SINTAIR 4 mg (chewable tablets)

SINTAIR 5 mg (chewable tablets)

SINTAIR 10 mg (tablets)

1. WHAT SINTAIR CONTAINS:

The active ingredient in **SINTAIR** is montelukast sodium.

- **SINTAIR 4 mg**: Each chewable tablet contains montelukast sodium, equivalent to 4 mg montelukast.
- **SINTAIR 5 mg**: Each chewable tablet contains montelukast sodium, equivalent to 5 mg montelukast.
- **SINTAIR 10 mg**: Each tablet contains montelukast sodium, equivalent to 10 mg montelukast.

In addition, **SINTAIR** contains the following inactive ingredients:

- **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.

SINTAIR tablets are sugar free.

SINTAIR tablets contain aspartame (see **Take special care with SINTAIR**).

2. WHAT SINTAIR IS USED FOR:

SINTAIR is medicine used to prevent and treat asthma.

SINTAIR is used to improve chronic asthma symptoms and to help prevent atopic asthma attacks (asthma induced by substances that cause allergies).

- **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 to 14 years of age.
- **SINTAIR 10 mg** tablets are used in adults and children from 15 years of age.

3. BEFORE YOU USE SINTAIR:

Do not take SINTAIR if:

- You are allergic (hypersensitive) to montelukast or any of the other ingredients of **SINTAIR**.
- You are pregnant or breastfeeding your baby.

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.

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.
- **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** need not be stopped during an acute attack.
- 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.
- You should seek medical attention 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 your or your child's asthma worsens during exercise, you should continue with your usual inhaled medication to prevent such occurrences. Your doctor will prescribe to you, additional inhaled medication 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 stop using that

suddenly 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 are aware that you or your child is sensitive to aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs such as ibuprofen) you should continue to avoid these medicines.
- You should seek medical attention if you or your child develop a skin rash or skin lesions, 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, anxious, have abnormal dreams, start seeing and hearing things, feel depressed, cannot sleep, are irritable and restless, start thinking about harming yourself, including suicidal ideas and experience tremors, after starting **SINTAIR** treatment.

Pregnancy and breastfeeding:

DO NOT use **SINTAIR** if you are pregnant, planning to become pregnant or breastfeeding your baby. Consult your doctor immediately if you suspect that you are pregnant.

Driving and using machinery:

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

Important information about some of the ingredients of SINTAIR:

SINTAIR contains aspartame as a sweetener. Aspartame is a source of phenylalanine (an essential amino acid of the body). Caution should be used if you or your child has a disorder called

phenylketonuria, which is a genetic disorder that is characterised by the inability of the body to utilise phenylalanine.

Taking SINTAIR with food or drink:

SINTAIR can be taken with or without food.

Using other medicines with SINTAIR:

If you or your child are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **SINTAIR** with these medicines, may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice.

- **SINTAIR** may routinely be used together with other medicines 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 agent), 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**, concurrent with phenobarbital (a sedative working on the central nervous system), phenytoin (an anti-convulsing medicine) or rifampicin (used for the treatment of tuberculosis).

4. HOW TO USE SINTAIR:

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

For the treatment of asthma, the dose for:

- children from 2 to 5 years old, is one **SINTAIR 4 mg** chewable tablet daily.

- children from 6 to 14 years old is one **SINTAIR 5 mg** chewable tablet daily.
- adults and children from 15 years and older is one **SINTAIR 10 mg** tablet daily.

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

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.

Do not share **SINTAIR** with any other person, even if their symptoms are the same as yours.

If you have any questions about the proper dose or usage of **SINTAIR**, ask your doctor.

If you or your child take more SINTAIR than you should:

Symptoms of an overdose may include, headache, vomiting, stomach pain, excessive (abnormal) movement, dilation of the pupil of the eyes, inability to sleep and thirst. In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you or your child forgets 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 the missed dose.

5. POSSIBLE SIDE-EFFECTS:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking SINTAIR, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following side-effects continue or are bothersome which may occur frequently:

- Skin rashes or skin lesions, headache, dizziness, sleeplessness, feeling unbalanced / spinning head, stuffy nose, coughing, flu, indigestion, stomach flu, stomach pain, tooth ache, runny stomach, thirst, pus in your urine, lack of strength / weakness, tiredness and a experiencing stress (trauma).

Check with your doctor if the following side-effect continue or is bothersome which may occur less frequent:

- Liver disease

The following rare side-effects have been reported and may occur:

- Increased tendency of bleeding, abnormal dreams, hearing and seeing things, feeling of irritable, aggressive, anxious or depressed, sleeplessness, restlessness, experiencing thoughts of suicide, experiencing sensations of tingling, burning, pricking, or numbness, experiencing sensations of reduced sense of touch, drowsiness, convulsions, nose bleeding, nausea, vomiting, runny stomach, indigestion, itching, skin hives, bruising of the skin, bone aches, muscle aches, muscle cramps and allergic reactions including, itching, swelling, skin rashes.

6. STORAGE AND DISPOSAL OF SINTAIR:

- Store at or below 25 °C.
- Keep in outer carton until required for use.
- Protect from moisture and light.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).