

SINCAST[®]

DESCRIPTION

SINCAST is the trade mark of Montelukast, an antiasthmatic and anti-allergic agent.

Each SINCAST 4 and 5 Chewable Tablet and SINCAST 10 Tablet, contains 4, 5 and 10mg of Montelukast, respectively, as Montelukast Sodium.

Excipients: Microcrystalline cellulose, lactose anhydrous, mannitol, croscarmellose sodium, aspartame, red iron oxide, hydroxypropyl cellulose, magnesium stearate, black mulberry powder, cherry powder.

CHEMISTRY

Montelukast Sodium is: Sodium 1-[[[(R)-m-[(E)-2-(7-chloro-2-quinolyl)-vinyl]- α -[α -(1-hydroxy-1-methylethyl)phenethyl]-benzyl]thio]methyl]cyclopropanecarboxylate.

CLINICAL PHARMACOLOGY

Montelukast is a leukotriene receptor antagonist. It blocks the naturally occurring chemicals in the lungs called leukotrienes which cause narrowing of the airways and inflammation in the lungs, which can lead to asthma symptoms.

Montelukast is rapidly absorbed following oral administration. It is extensively metabolized and more than 99% bound to plasma proteins.

INDICATIONS

- SINCAST is indicated for treatment of asthma. It also helps prevent asthma symptoms which are triggered by exercise.
- SINCAST may be used together with other anti-asthmatic drugs.

DOSAGE

The usual adult dose (15 years and above):

One SINCAST 10 Tablet per day, at bedtime, with or without food.

The usual Pediatric dose:

- 2-5 years: one SINCAST 4 Chewable Tablet daily.
- 6-14 years: one SINCAST 5 Chewable Tablet daily.

Notes

- The safety and effectiveness of SINCAST in children younger than 2 years old have not yet been established.
- SINCAST 4 and 5 Chewable Tablets should be taken either one hour before, or two hours after food, and should be chewed.
- It is important that SINCAST tablets are taken daily at bedtime or as prescribed by the physician, even when there are no symptoms or if an asthma attack is experienced.
- If a SINCAST dose is missed, compensation should not be attempted by taking an extra tablet; dosing should be carried on with the next dose as usual.

ADVERSE EFFECTS

Abdominal pain, headache, fever, trauma, infectious gastroenteritis, toothache, nasal congestion, cough and influenza, sore throat and sinusitis, restlessness and irritability, weakness and tiredness, joint pain, dizziness, dry mouth, indigestion, inability to sleep, a general feeling of being unwell, muscle pain, diarrhea, nausea and vomiting, allergic reaction including swelling of the face, lips, tongue and/or throat, itching, rash or hives.

USE IN PREGNANCY

Women who are pregnant, intend to become pregnant, or think they might be pregnant should consult their physician before using Montelukast. FDA Pregnancy Category B.

USE IN LACTATION

It is not known whether Montelukast is distributed in human breast milk. Accordingly, women who are breast-feeding a baby, or intend to breast feed, should consult their physician before taking Montelukast.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Not Documented.

DRUG INTERACTIONS

The physician should be informed of other medicines used, including non-prescribed drugs. The physician should be informed, in particular, if phenytoin, phenobarbitone or rifampicin are used.

CONTRAINDICATIONS

Allergy to Montelukast.

WARNINGS

- Patients with known aspirin sensitivity should be advised to continue avoidance of aspirin or other nonsteroidal anti-inflammatory agents while taking Montelukast.
- Montelukast is not intended for the treatment of a sudden attack of breathlessness; it will not help and should not be used in this situation.
- Montelukast should be discontinued and immediate medical attention sought if allergic reactions are experienced.
- Medical attention should be sought immediately if a combination of any of the following is experienced: flu-like illness, increasing breathlessness, pins and needles or numbness of limbs and/or rash.

OVERDOSE

No specific information is available on the treatment of overdose with Montelukast. In the event of overdose, it is reasonable to employ the usual supportive measures; e.g., removing unabsorbed material from the gastrointestinal tract, employing clinical monitoring, and instituting supportive therapy, if required.

PRECAUTIONS

- Montelukast should not replace steroid medications that are already being used.
- If a beta-agonist inhaler is being used more than usual along with Montelukast, the physician should be consulted.

HOW SUPPLIED

- Boxes of 28 Chewable Tablets of SINCAST 4.
- Boxes of 30 Chewable Tablets of SINCAST 5.
- Boxes of 30 Tablets of SINCAST 10.
- Hospital packs of different presentations.

Store according to conditions specified on the package.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
 - The doctor and the pharmacist are experts in medicine.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
 - Keep medicaments out of the reach of children.
- Issued in September 2011

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request



THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO.(P.L.C.)
P.O. BOX 94, NAQR 11710, JORDAN