United Pharmaceuticals

# UNICAST®

## Montelukast Sodium

**Description:**

UNICAST® (Montelukast Sodium) is a selective and orally active leukotriene receptor antagonist that binds with high affinity and selectivity to inhibit the cysteinyl leukotriene CysLT1 receptor. It blocks leukotrienes, the naturally occurring chemicals in the lungs, which cause narrowing of the airways and inflammation in the lungs which can lead to asthma symptoms. Leukotrienes also contribute to the symptoms of allergy; therefore blocking leukotrienes improves seasonal allergy symptoms.

**Properties:**

Montelukast is rapidly absorbed following oral administration with more than 99% bound to plasma proteins. Montelukast has minimal distribution across the blood-brain barrier, while the steady state volume of distribution of Montelukast averages 8 to 11 liters.
Montelukast is extensively metabolized but with undetectable plasma concentrations of metabolites at steady state in adults and pediatric patients.
The plasma clearance of Montelukast averages 45 ml/min in healthy adults. Montelukast and its metabolites are excreted almost exclusively via the bile.
The plasma half-life of Montelukast is slightly longer in the elderly. No dosage adjustment is required in the elderly patients, in patients with mild to moderate hepatic insufficiency and in renal insufficiency patients.

**Indications:**

UNICAST® is prescribed for the treatment of:
- ***Asthma:*** UNICAST® is used for the long-term treatment of asthmatic patients, adults and children ages 12 months and older who are not adequately controlled on their asthma medications and need additional therapy. Montelukast should not be used for the immediate relief of an asthma attack.
- ***Prevention of exercise-induced asthma:*** UNICAST® is used for the prevention of exercise-induced asthma in patients 15 years of age and older.
- ***Allergic Rhinitis:*** UNICAST® is used to help control the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose).

UNICAST® is used to treat seasonal allergic rhinitis in adults and children ages 2 years and older, and treatment perennial allergic rhinitis in adults and children ages 6 months and older.

**Dosage and administration:**

***Children, 2 to 5 years:*** The usual dose is one UNICAST® 4 mg chewable tablet daily.
***Children, 6 to 14 years:*** The usual dose is one UNICAST® 5 mg chewable tablet daily.
***Adults and adolescents 15 years of age and older:*** The usual dose is one UNICAST® 10 mg tablet daily.
***Patient notes:***
- UNICAST® is administered in the evening, at bedtime, without regard to food intake and should be chewed (UNICAST® 4 & 5 mg chewable tablets) or taken (UNICAST® 10 mg tablets) at about the same time each day.
- UNICAST® should not be used together with other products that contain the same active ingredient.
- It is important to continue taking UNICAST® in the presence or absence of symptoms, for as long as the doctor prescribes it, in order to help maintain control of the patient's asthma. UNICAST® can treat asthma only with continued use.
- For exercise-induced asthma, the patient should take UNICAST® at least 2 hours before exercise, but not more than once daily.

***- Measures used that helps reducing the severity of asthma symptoms and the frequency of asthma attacks:***

○ Avoid or reduce contact with conditions that may trigger an asthma episode (e.g. smoking including passive smoking, house dust mites, cockroaches, moulds, pollen, animal dander, changes in weather and temperature and infections in the upper airway such as colds).
○ Develop a treatment plan that best controls asthma, which includes proper use of all prescribed medication for asthma.

**Contraindications:**

Hypersensitivity to Montelukast or any of the excipients available in the product.

**Precautions:**

- UNICAST® 4 mg chewable tablets are for children aged 2 to 5 years but not recommended for use in children less than two years of age since the safety and effectiveness of Montelukast in children younger than 2 years old have not been established yet.
- UNICAST® 5 mg chewable tablets are for children aged 6 to 14 years while UNICAST® 10 mg tablets are not recommended for use in children under 15 years of age.
- UNICAST® 4 mg & 5 mg chewable tablets contain Aspartame, a source of phenylalanine. The phenylalanine in the tablets may be harmful to patients with phenylketonuria.
- UNICAST® 10 mg tablets contain Lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Montelukast.
- Montelukast is not intended for the treatment of sudden attack of breathlessness and should never be used for this purpose. If an attack occurs, the instructions that the doctor has given should be followed exactly. It is very important to have the medication needed for such an attack (i.e. a short acting inhaled beta-agonist) readily accessible at all times.
- It is important that the patient uses all the asthma medication prescribed by the doctor as intended. Montelukast should not replace steroid medications (whether inhaled or taken by mouth) that the patient may already be using.
- Patients with Aspirin-sensitive asthma and who taking Montelukast, must continue the treatment and to avoid taking Aspirin or other non-steroidal anti-inflammatory drugs.
- In adults Montelukast is not expected to affect their ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects such as drowsiness that have been reported very rarely with Montelukast which may affect the patient's ability to drive or operate machinery.
- If the patient misses a dose, he takes the next one as usual without taking an extra tablet, just resume the usual schedule of one tablet, once daily from UNICAST®. If too many tablets are taken by mistake, as with all medicines, a doctor should be contacted or the patient should be taken to hospital, immediately.

**Use during pregnancy and lactation:**

Pregnancy category **B**
***Pregnancy:*** If there is any suspicion of pregnancy in a female patient who has been prescribed Montelukast, the doctor should be consulted before the tablets are taken.
***Lactation:*** It is not known whether Montelukast is present in human breast-milk. The doctor should be consulted before Montelukast is taken, if a female patient is breast feeding or intending to breast feed a baby.

**Drug interactions:**

- Montelukast is a potent inhibitor of P450 2C8, but no in vivo drug interaction studies have been conducted between Montelukast and cytochrome P450 2C8 substrates. Caution should be exercised when Montelukast is concomitantly administered with a cytochrome P450 2C8 substrate, such as Paclitaxel, Rosiglitazone,and Repaglinide.
- If the patient suffers from asthma and if the asthma is made worse by Aspirin, the patient should continue avoiding Aspirin or other non-steroidal anti-inflammatory drugs while taking Montelukast.
- Phenobarbital, which induces hepatic metabolism, decreased the AUC of Montelukast approximately 40% following a single 10 mg dose of Montelukast. No dosage adjustment for Montelukast is recommended. It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers, such as Phenobarbital or Rifampin are co-administered with Montelukast.

**Side effects:**

Like all medicines Montelukast can have side effects, in some patients.
In clinical studies with Montelukast in children, the most frequently reported side effects thought to be related to treatment with Montelukast were headache and thirst.
Other side effects reported in children were cough, sore throat, fever, diarrhea, nausea, influenza and sinusitis, although it is not certain that these were caused by Montelukast.
In studies in adult patients, abdominal pain and headache were the most frequently reported side effects thought to be related to treatment with Montelukast.
Other side effects reported in adults were fever, trauma, infectious gastro-enteritis, toothache, nasal congestion, cough and influenza, although it is not certain that these were caused by Montelukast.
The following side effects have also been reported in adults and/or children: Weakness and tiredness, restlessness, agitation including aggressive behavior, irritability, joint pains, dizziness, dry mouth, indigestion, drowsiness, hallucinations, dream abnormalities including nightmares, inability to sleep, a general feeling of being unwell, pins and needles/numbness, seizure, muscle pains, diarrhea, nausea and vomiting, hepatitis, palpitations, increased bleeding tendency, bruising and swelling due to fluid retention.
Allergic reactions have also been reported which included swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, itching, rash or hives. It is vital that the patient stops taking Montelukast and seek immediate medical attention if he experiences an allergic reaction.
Very rare cases of condition known as Churg-strauss syndrome have been reported during Montelukast treatment in asthmatic patients. If the patient experiences a combination of any of the following symptoms, particularly if they are persistent or worsening, seek medical attention immediately: Flu-like illness, increasing breathlessness, pins and needles or numbness of limbs, and/or rash.

**Overdosage:**

In the event of overdose, it is reasonable to employ the usual supportive measures; e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring and institute supportive therapy, if required.
There were no side effects reported in the majority of overdosage reports. The most frequent side effects observed were thirst, somnolence, mydriasis, hyperkinesia, and abdominal pain.
It is not known whether Montelukast is removed by peritoneal dialysis or hemodialysis.

**Storage conditions:**

Store up to 30ºC, protected from light and moisture.

**Presentation:**

UNICAST® 4: Each chewable tablet contains Montelukast Sodium equivalent to 4 mg Montelukast in packs of 30 tablets.
UNICAST® 5: Each chewable tablet contains Montelukast Sodium equivalent to 5 mg Montelukast in packs of 30 tablets.
UNICAST® 10: Each film coated tablet contains Montelukast Sodium equivalent to 10 mg Montelukast in packs of 30 tablets.
*Hospital packs are also available.*

**Excipients:**

UNICAST® 4 & 5: Microcrystalline Cellulose, Cross Povidone, Crosscarmellose Sodium, Magnesium Stearate, Opadry white Y-YL-7000, Red Iron Oxide, Cherry Flavor, Aspartam & Mg Stearate.
UNICAST® 10: Microcrystalline Cellulose, Lactose Anhydrous, Crosscarmellose Sodium , Hydroxypropyl Cellulose, Mg Stearate, Opadry white Y-1-7000, Yellow Iron Oxide & Red Iron Oxide.

**This is a medicament**

· 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 sold the medicament.
· The doctor and the pharmacist are experts in medicine, its benefits and risks.
· Do not by yourself interrupt the period of treatment prescribed for you.
· Do not repeat the same prescription without consulting your doctor.
· Keep medicament out of the reach of children.

**COUNCIL OF ARAB HEALTH MINISTERS**
**UNION OF ARAB PHARMACISTS**

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