

# Montal<sup>®</sup> 10



Montelukast 10mg (as Montelukast Sodium)

## Presentation:

**Montal<sup>®</sup> 10:** Each film coated tablet contains Montelukast Sodium equivalent to 10 mg Montelukast in packs of 30 tablets.

Hospital packs are also available (500 and 1000).

Note: Not all pack sizes are available in all countries.

**Excipients:** Mannitol, croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, magnesium stearate, Lactose monohydrate, opadry yellow.

## Pharmaceutical form:

Film coated tablets.

## Pharmacotherapeutic group:

Leukotriene receptor antagonist. ATC: R03DC03.

## Therapeutic Indications:

- Your doctor has prescribed **Montal<sup>®</sup>** to treat asthma, preventing your asthma symptoms during the day and night.
- **Montal<sup>®</sup>** is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- **Montal<sup>®</sup>** also helps prevent the narrowing of airways triggered by exercise.

In those asthmatic patients in whom **Montal<sup>®</sup>** is indicated in asthma, **Montal<sup>®</sup>** can also provide symptomatic relief of seasonal allergic rhinitis.

- Montelukast should only be reserved to treat allergic rhinitis in patients who are not treated effectively with or cannot tolerate other allergy medicines.

## Posology and method of administration:

- To be taken by mouth
- You should take only one tablet of **Montal<sup>®</sup>** once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take **Montal<sup>®</sup>** as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- If you have any further questions on the use of this product, ask your child's doctor or pharmacist.
- If you or your child is taking **Montal<sup>®</sup>**, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

## Dosage

**For adults 15 years of age and older:** One 10 mg tablet to be taken daily in the evening. **Montal<sup>®</sup>** 10 mg may be taken with or without food.

**Forgotten dose:** Try to take **Montal<sup>®</sup>** as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily. Do not take a double dose to make up for a forgotten dose.

**Stopped treatment:** **Montal<sup>®</sup>** can treat your asthma only if you continue to take it. It is important to continue taking **Montal<sup>®</sup>** for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## Contra-indications:

If you are allergic (hypersensitive) to montelukast or any of the excipients.

## Warnings and Precautions for use:

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. **Montal<sup>®</sup>** should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.
- Use in children less than 2 years old: Use in this age have not been established.
- For Children 2 – 5 years old, **Montal<sup>®</sup>** paediatrics 4mg chewable tablets are available.
- For Children 6 – 14 years old, **Montal<sup>®</sup>** paediatrics 5mg chewable tablets are available.
- **Montal<sup>®</sup>** 10 mg may be taken with or without food.

**Driving and using machines:** **Montal<sup>®</sup>** is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with **Montal<sup>®</sup>** may affect some patients' ability to drive or operate machinery.

**Important information about some of the ingredients of Montal<sup>®</sup>:**  
**Montal<sup>®</sup>** 10 mg film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **Montal<sup>®</sup>**.

## Use During Pregnancy and Lactation:

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast. Your doctor will assess whether you can take **Montal<sup>®</sup>** during this time.

**Lactation:** It is not known if Montelukast appears in breast milk. You should consult your doctor before taking **Montal<sup>®</sup>** if you are breast-feeding or intend to breast-feed.

## Drug Interactions:

Some medicines may affect how Montelukast works, or Montelukast may affect how other medicines work.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Tell your doctor if you are taking the following medicines before starting **Montal<sup>®</sup>**:

- Phenobarbital & Phenytoin (used for treatment of epilepsy).
- Rifampicin (used to treat tuberculosis and some other infections).

## Undesirable effects:

Like all medicines, Montelukast can cause side effects, although not everybody gets them.

In clinical studies with Montelukast tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to Montelukast were: abdominal pain and headache.

These were usually mild and occurred at a greater frequency in patients treated with Montelukast than placebo (a pill containing no medication). The frequency of possible side effects listed below is defined using the following convention: Very common (affects at least 1 user in 10), Common (affects 1 to 10 users in 100), Uncommon (affects 1 to 10 users in 1,000), Rare (affects 1 to 10 users in 10,000), Very rare (affects less than 1 user in 10,000).

Additionally, while the medicine has been on the market, the following have been reported:

- Upper respiratory infection (Very common)
- Increased bleeding tendency (Rare)
- Allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (Uncommon)
- Serious behavior and mood-related changes include suicidal thoughts and actions.
- Behavior and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restless, agitation including aggressive behavior or hostility, depression (Uncommon); tremor (Rare); hallucinations, suicidal thoughts and actions (Very rare)]
- Dizziness, drowsiness, pins and needles/numbness, seizure (Uncommon).
- Palpitations (Rare).
- Nosebleed (Uncommon).
- Diarrhea, nausea, vomiting (Common); dry mouth, indigestion (Uncommon).
- Hepatitis (inflammation of the liver) (Very rare).
- Bruising, itching, hives (Uncommon); tender red lumps under the skin most commonly on your shins (erythema nodosum) (Very rare).
- Joint or muscle pain, muscle cramps (Uncommon).
- Fever (Common); tiredness, feeling unwell, swelling (Uncommon).

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms.

• Stuttering (Dysphemia) and obsessive-compulsive symptoms as very rare potential neuropsychiatric adverse events.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## Reporting of suspected adverse reactions

Tel: 06-5632000

Website: [www.jfda.jo](http://www.jfda.jo)

Smart phones application: Jordan fda

Paper reporting form: yellow card

## Overdose:

Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

## Pharmacological Properties:

### Pharmacodynamic properties

**Montal<sup>®</sup>** (Montelukast Sodium) is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, **Montal<sup>®</sup>** improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

### Pharmacokinetic properties

**Absorption:** Montelukast is rapidly absorbed following oral administration. **Distribution:** Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of Montelukast averages 8-11 liters. **Elimination:** The plasma clearance of Montelukast averages 45 ml/min in healthy adults. Montelukast and its metabolites are excreted almost exclusively via the bile.

## Special precautions for storage:

Do not store above 30°C.

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### 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 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.

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