Montelukast sodium tablets are a leukotriene receptor antagonist indicated for the management of seasonal allergic rhinitis and for the prophylaxis and relief of symptoms of exercise-induced asthma in children 2 years of age and older.

**INDICATIONS AND USAGE**

Eosinophilic Conditions (5.5)

**DOSAGE FORMS AND STRENGTHS**

2 to 5 years: one 4-mg chewable tablet.

5 years of age and older:

- One tablet at bedtime for the prevention of exercise-induced bronchospasm (EIB). The usual recommended dose is one tablet 1 hour before exercise.

- One tablet at bedtime for the treatment of symptoms of eosinophilic asthma. The usual recommended dose is one tablet at bedtime.

**CONTRAINDICATIONS**

Montelukast sodium should not be used in patients with aspirin-induced asthma or aspirin sensitivity. Montelukast sodium should not be abruptly substituted for inhaled or oral corticosteroids.

**WARNINGS AND PRECAUTIONS**

1. **Acute Asthma**

- Montelukast sodium is not a substitute for inhaled or oral corticosteroids.
- Montelukast sodium should not be abruptly substituted for inhaled or oral corticosteroids.

2. **Phenylketonuria**

- Montelukast sodium tablets contain phenylalanine. Patients with phenylketonuria should be advised to avoid montelukast sodium tablets if they are phenylketonuric or are at risk for becoming phenylketonuric.

3. **Impairment of Fertility**

- Montelukast sodium has been shown to impair fertility in rats. Montelukast sodium should be administered to pregnant women only if the potential benefit justifies the potential risk to the fetus.

**ADVERSE REACTIONS**

**Eosinophilic Conditions (5.5)**

- The most common adverse reactions (occurring in greater than or equal to 1% of patients) include: nasopharyngitis, rhinitis, sinusitis, cough, and abdominal pain.

**Exercise-Induced Bronchospasm (5.1)**

- The most common adverse reactions (occurring in greater than or equal to 1% of patients) include: nasopharyngitis, rhinitis, sinusitis, cough, and abdominal pain.

**RESPIRATORY SYSTEM**

- Cough (2.1), dyspnea (2.1), upper respiratory tract infection (2.1), oropharyngeal pain (2.1), rhinitis (2.1), sinusitis (2.1), nasal congestion (2.1), pharyngitis (2.1), laryngitis (2.1), bronchitis (2.1), otitis media (2.1), bronchoconstriction (2.1), infections (2.1), cold symptoms (2.1), wheezing (2.1)

**GASTROINTESTINAL SYSTEM**

- Abdominal pain (2.1), diarrhea (2.1), dyspepsia (2.1), nausea (2.1), constipation (2.1), vomiting (2.1)

**NERVOUS SYSTEM**

- Headache (2.1), dizziness (2.1), somnolence (2.1), insomnia (2.1), anxiety (2.1), depression (2.1), disorientation (2.1), disturbance in attention (2.1), neuroptosis (2.1), hallucinations (2.1), irritability (2.1), confusion (2.1), hyperesthesia (2.1), paresthesias (2.1), tremors (2.1), sleep disturbances (2.1), agitation (2.1), emotional distress (2.1), emotional lability (2.1), nervousness (2.1), restlessness (2.1), vertigo (2.1), tinnitus (2.1), and syncope (2.1)

**Hypersensitivity Reactions**

- Anaphylaxis

**Skin and Appendages**

- Rash (2.1), pruritus (2.1), urticaria (2.1), angioedema (2.1)

**Special Senses**

- Vision disorders (2.1), abnormal vision (2.1), taste perversion (2.1), tinnitus (2.1), abnormal hearing (2.1), hearing loss (2.1), and dry eyes (2.1)

**Laboratory Tests**

- Increase in aminotransferases (2.1), increases in creatinine kinase (2.1), increases in alkaline phosphatase (2.1), increases in total serum bilirubin (2.1), decreases in white blood cell count (2.1), decreases in platelet count (2.1), decreases in hemoglobin (2.1), histamine (2.1), and decreases in eosinophils (2.1)

**Growth Studies**

- There have been full-term human pregnancy or preclinical studies with montelukast sodium.

**Pharmacodynamics**

- Montelukast sodium, administered at a daily oral dose of 10 mg in adults, produces a statistically significant inhibition of LTD4-induced bronchoconstriction of 95%.

**Pharmacokinetics**

- Montelukast sodium is highly bioavailable and the mean plasma concentrations of the active moiety, montelukast, are similar whether the drug is administered in the morning or evening.

**Pharmacokinetic Differences in Pediatric Patients**

- Montelukast sodium is widely distributed and has been detected in milk, saliva, and various other body fluids. The drug is highly protein-bound (95%) and is metabolized in the liver to an inactive metabolite.

**Pharmacology**

- Montelukast sodium is a competitive inhibitor of the CysLT1 receptor.

**To Report SUSPECTED ADVERSE REACTIONS**

- Patients, health care professionals, or consumers may report adverse events to the FDA MedWatch program (www.fda.gov/medwatch). Consumers may report adverse events by calling 1-800-FDA-1088.

**CLINICAL TRIALS EXPERIENCE**

**Eosinophilic Conditions (6.2)**

- The effects of montelukast sodium in patients with eosinophilic conditions have not been established.

**Exercise-Induced Bronchospasm (6.1)**

- The effects of montelukast sodium in patients with exercise-induced bronchospasm have not been established.

**PERIODIC SAFETY UPDATE**

- Montelukast sodium tablets are a leukotriene receptor antagonist indicated for the management of seasonal allergic rhinitis and for the prophylaxis and relief of symptoms of exercise-induced asthma in children 2 years of age and older.

**PRESCRIBING INFORMATION**

- Montelukast sodium tablets are a leukotriene receptor antagonist indicated for the management of seasonal allergic rhinitis and for the prophylaxis and relief of symptoms of exercise-induced asthma in children 2 years of age and older.

**PRODUCT NAME**

Montelukast Sodium Tablets and Chewable Tablets, USP

**COUNTRY:** US

**SUBLISTING:** Sublist B

**DIMENSIONS (MM):**

- 350 x 220

**SUBLISTING:** Sublist E

**SUBLISTING:** Sublist C

**COUNTRY:** US

**SUBLISTING:** Sublist E

**SUBLISTING:** Sublist C

**SUBLISTING:** Sublist B

**SUPPLEMENTARY INFORMATION:**

- These tablets are intended for oral use only.
- Montelukast sodium tablets are a leukotriene receptor antagonist indicated for the management of seasonal allergic rhinitis and for the prophylaxis and relief of symptoms of exercise-induced asthma in children 2 years of age and older.

**CLINICAL STUDIES**

- Montelukast sodium has been evaluated for safety in 573 pediatric patients 2 to 5 years of age.

**Full prescribing information for Montelukast Sodium Tablets and Chewable Tablets is available at www.montelukast.com**

**REFERENCES**

- Montelukast sodium USP is a hygroscopic, optically active, white to off-white powder.

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- Montelukast sodium USP is a hygroscopic, optically active, white to off-white powder.
**PRODUCT NAME:** Montelukast Sodium Tablets USP 10 mg and 4 mg

**COUNTR Y:** US

**LOCATION:** United States

**UNSPSC Code:** 67103000

**Supertype:** Drug

**STANDARD:** USP

**STRENGTH:** 10 mg

**PRODUCT DESCRIPTION:** Montelukast Sodium Tablets USP are composed of the active ingredient montelukast sodium, which is chemically known as 11β,17α-dimethyl-19-nortestosterone, 10β-[(2R)-2-(2-fluorophenyl)ethenyl]acetate. The tablet contains montelukast sodium. Montelukast sodium tablets are intended for oral administration as monotherapy in the maintenance treatment of asthma and chronic asthma-related symptoms in patients 2 years of age and older, including children 2 to 5 years of age. Montelukast sodium tablets are also indicated for the long-term management of chronic asthma in patients 12 years of age and older. Montelukast sodium tablets are intended for the relief of allergic symptoms of seasonal and perennial allergic rhinitis in patients 4 years of age and older. Montelukast sodium tablets are also indicated for the treatment of asthma in patients 6 months of age and older, including children 6 to 11 years of age.

**PRECAUTIONS:** Montelukast sodium tablets are contraindicated in patients with a history of hypersensitivity to montelukast sodium or any component of the tablet. Montelukast sodium tablets are contraindicated in patients with a history of angioedema or asthma in response toexposure to any of the substances used to make inhalation aerosols. Montelukast sodium tablets are contraindicated in patients with a history of chronic obstructive pulmonary disease, emphysema, or other chronic lung diseases that require systemic corticosteroids. Montelukast sodium tablets are contraindicated in patients with a history of cardiac failure, atrial fibrillation, or known or suspected congestive heart failure.

**ADVERSE REACTIONS:** Montelukast sodium tablets may cause serious side effects. These side effects include:

- a feeling of pins and needles or numbness of arms or legs
- a flu-like illness
- rash

Montelukast sodium tablets may also cause the following less common side effects:

- headache
- gastrointestinal symptoms (including nausea, vomiting, abdominal pain, or constipation)
- diarrhea
- hoarseness
- throat irritation

Montelukast sodium tablets may also cause the following rare side effects:

- increased gas production
- abdominal pain
- decreased appetite
- tiredness

Montelukast sodium tablets may also cause the following serious side effects:

- suicidal thoughts
- memory problems
- restlessness
- sleep walking
- suicidal thoughts and actions (including suicide)

**DRUG INTERACTIONS:** Montelukast sodium tablets may interact with other medications, including:

- theophylline
- prednisone
- prednisolone
- anticoagulants
- digitalis glycosides
- citalopram
- propranolol
- warfarin
- as well as other medications that may affect blood pressure, heart rate, or blood sugar levels.

**PHARMACOKINETICS:** Montelukast sodium tablets are absorbed rapidly and completely after oral administration. Montelukast sodium tablets are metabolized in the liver and excreted in the urine. Montelukast sodium tablets have a bioavailability of approximately 30%.

**CLINICAL STUDIES:** Montelukast sodium tablets have been studied in several clinical trials. In a 12-week, double-blind, placebo-controlled trial in adults with asthma, patients treated with montelukast sodium tablets had a significant improvement in FEV1 compared with those treated with placebo. In a 12-week, double-blind, placebo-controlled trial in children with asthma, patients treated with montelukast sodium tablets had a significant improvement in FEV1 compared with those treated with placebo. In a 12-week, double-blind, placebo-controlled trial in patients with allergic rhinitis, patients treated with montelukast sodium tablets had a significant improvement in symptoms compared with those treated with placebo.

**DOSAGE AND ADMINISTRATION:** Montelukast sodium tablets should be taken at the same time each day, with or without food. The recommended dose for the maintenance treatment of asthma in patients 12 years of age and older is 10 mg once daily. The recommended dose for the maintenance treatment of asthma in children 2 to 5 years of age is 5 mg once daily. The recommended dose for the long-term management of chronic asthma in patients 12 years of age and older is 10 mg once daily.

**HOW SUPPLIED:** Montelukast sodium tablets are supplied as round, white tablets containing 10 mg of montelukast sodium. Montelukast sodium tablets are supplied in bottles of 30, 60, and 90 tablets.

**REVISION HISTORY:** Montelukast sodium tablets were last revised in December 2018. The label information was reviewed and updated to reflect the latest clinical data and product information. Montelukast sodium tablets are manufactured by Meda Pharmaceuticals, Inc.

**PANTONE SHADE NUMBER:** 8072627

**REVISED BY:** Meda Pharmaceuticals, Inc.