

Montisel[®] Tablet / Sachet

(Montelukast)

مونٹیلوکاسٹ
ٹیبلٹ / سیکٹ

COMPOSITION:

Montisel Tablet 10mg

Each film coated tablet contains:
Montelukast (as Sodium).....10mg
(USP Specification)

Montisel Sachet 4mg

Each sachet contains:
Montelukast sodium equivalent to Montelukast.....4mg
(USP Specification)

DESCRIPTION:

Montisel (Montelukast) is a leukotriene receptor antagonist, acts selectively, specifically inhibiting the cysteinyl leukotriene receptor. It is orally active.

INDICATIONS:

- Prophylaxis and treatment of chronic asthma
- Prevention of day and night time asthma symptoms.
- Treatment of aspirin sensitive asthmatic patients.
- Prevention of exercise induced bronchoconstriction.
- Day and night time symptoms of seasonal and perennial allergic rhinitis.

DOSE AND ADMINISTRATION:

Asthma

Montisel should be taken once daily in the evening. The following doses are recommended:

For adults and adolescents 15 years of age and older: one 10-mg tablet.

For pediatric patients 12 months to 5 years of age: One packet of 4-mg oral granules.

Safety and effectiveness in pediatric patients less than 12 months of age with asthma have not been established.

Exercise-Induced Bronchoconstriction (EIB)

For prevention of EIB, a single dose of **Montisel** should be taken at least 2 hours before exercise. The following doses are recommended:

For adults and adolescents 15 years of age and older: one 10-mg tablet.

An additional dose of **Montisel** should not be taken within 24 hours of a previous dose. Patients already taking **Montisel** daily for another indication (including chronic asthma) should not take an additional dose to prevent EIB. All patients should have available for rescue a short-acting β -agonist. Safety and efficacy in patients younger than 6 years of age have not been established. Daily administration of **Montisel** for the chronic treatment of asthma has not been established to prevent acute episodes of EIB.

Allergic Rhinitis

For allergic rhinitis, **Montisel** should be taken once daily. Efficacy was demonstrated for seasonal allergic rhinitis when montelukast was administered in the morning or the evening without regard to time of food ingestion. The time of administration may be individualized to suit patient needs.

The following doses for the treatment of symptoms of seasonal allergic rhinitis are recommended:

For adults and adolescents 15 years of age and older: one 10-mg tablet.

For pediatric patients 12 months to 5 years of age: One packet of 4-mg oral granules.

Safety and effectiveness in pediatric patients younger than 2 years of age with seasonal allergic rhinitis have not been established.

The following doses for the treatment of symptoms of perennial allergic rhinitis are recommended:

For adults and adolescents 15 years of age and older: one 10-mg tablet.

For pediatric patients 12 months to 5 years of age: One packet of 4-mg oral granules.

Safety and effectiveness in pediatric patients younger than 6 months of age with perennial allergic rhinitis have not been established.

Asthma and Allergic Rhinitis

Patients with both asthma and allergic rhinitis should take only one **Montisel** dose daily in the evening.

CONCOMITANT USE WITH BRONCHODILATORS:

Montisel tablets/sachet can be co-prescribed with inhaled corticosteroids when asthma is not well managed with the latter alone. However, the dose of inhaled corticosteroids afterwards is gradually reduced or tapered off completely after getting adequate clinical response with the combination. However, **Montisel** tablets should not be an abrupt replacement for inhaled steroids.

Montisel tablets/sachet may be taken irrespective of food.

Montisel starts exhibiting its therapeutic effect in terms of control parameters within on day of commencement of therapy, patient should continue using **Montisel** even during periods of exacerbation of asthma symptoms.

USE IN OLD AGE COMPROMISED RENAL / HEPATIC

FUNCTION:

There is no need to adjust dose in elderly patients, renal dysfunction, or hepatic dysfunction.

CONTRAINDICATIONS:

Montisel tablets/sachet are contraindicated in case of history hypersensitivity to Montelukast or any other ingredient of the product and also contraindicated in lactation.

PRECAUTIONS:

Do not substitute for steroid therapy or use for acute attacks. discontinue if an eosinophilic condition or a churg-strauss syndrome develops. If signs and symptoms of hepato-toxicity, measure serum transaminases and consider withdrawing therapy.

USE IN CHILDREN:

Not recommended under 6 years.

DRUG INTERACTIONS:

Montisel may not be co-administered with the drugs such as Phenobarbitone, Phenytoin and Rifampicin.

ADVERSE EFFECTS:

The adverse effects related to **Montisel** are the abdominal pain and headache.

SIDE EFFECTS:

Montisel is overall well tolerated its common side effects include asthenia, dyspepsia, dizziness and flu like symptoms. side effects are usually mild and do not require therapy withdrawal.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on prescription of registered medical practitioner only.

HOW SUPPLIED:

Montisel Tablet 10mg

14 Tablets.

Montisel Sachet 4mg

14 Sachets.

خوراک و طریقہ استعمال:

14 ٹیبلٹس۔
14 سیکٹس۔

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

**PHARMASOL
PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.