

MONTEXIN CHEWABLE TABLETS

Montelukast (4mg, 5mg)

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What *Montexin* is used for

1. Prevention and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.
2. The relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older).

How *Montexin* works

Montexin contains an active ingredient montelukast.

Montelukast 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, it improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms.

Before you use *Montexin*

When you must not use it

Do not use *Montexin* if you had an allergic reaction (hypersensitivity) to montelukast or any other ingredients listed at the end of this leaflet.

Pregnancy and lactation

Do not take *Montexin* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *Montexin*, stop taking it immediately and contact your doctor.

Do not take *Montexin* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Tell your doctor before you start taking your tablets if you:

- have phenylketonuria (inherited disorder that causes an amino acid called phenylalanine to build up in your body)
- are allergic to aspirin.
- have had an allergy to any other medicines, foods, preservatives or dyes.

Montexin is not indicated for acute asthma attacks.

It should not be used as a single therapy for the treatment and management of bronchospasm (constriction of the airways going into the lungs) caused by exercise.

Your doctor will discuss the risks and benefits involved.

Taking other medicines

Other medicines may be affected by *Montexin*. They, in turn, may affect how well *Montexin* works. These include:

- Theophylline
- Prednisone
- Prednisolone
- Oral contraceptives (norethindrone 1 mg/ethinyl estradiol 35 mcg)
- Terfenadine
- Digoxin
- Warfarin
- Cytochrome P450 enzyme inducers (eg., Phenobarbital or rifampin)

Tell your doctor if you are taking above-mentioned medicines or any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How to use *Montexin*

How much to use

Montexin should be taken once a day with water.

Asthma or seasonal allergic rhinitis

Children 6 to 14 years of age: one 5mg chewable tablet daily

Children 2 to 5 years of age: one 4mg chewable tablet daily

When to use it

For asthma, *Montexin* should be taken in the evening. For seasonal allergic

rhinitis, the time of taking may be individualized to suit your own needs. If you have both asthma and allergic rhinitis, please take in the evening.

You can take your tablets with or without food.

How long to use it

Your doctor can provide you with further information. Do not stop taking *Montexin* or change when you take it without talking with your doctor.

You are advised to continue taking *Montexin* while your asthma is controlled, as well as during periods of worsening asthma.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The sign of overdose include:

- Abdominal pain
- Sleepiness
- Thirst
- Headache
- Vomit
- Psychomotor hyperactivity

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Montexin*.

Tell your doctor immediately if you become pregnant while taking this medication

If you are sensitive to aspirin, continue to avoid taking aspirin or other medicines called non-steroidal anti-

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inflammatory drugs (NSAIDs) while taking *Montexin* tablet.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Montexin* to anyone else, even if they have the same symptoms or condition as you.

Do not take *Montexin* if you need relief right away from a sudden asthma attack. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attack.

Things to be careful of

Always have your rescue inhaler medicine with you for asthma attacks.

Do not stop taking or lower the dose of your other asthma medicines unless your doctor tells you to.

Side effects

Like all medicines, *Montexin* can cause side effects, although not everybody gets them. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet please consult your doctor or pharmacist.

Asthma

Adults 15 Years of Age and Older

Body As A Whole:

Asthenia/fatigue, fever, abdominal pain, trauma

Digestive System Disorder:

Dyspepsia (indigestion), gastroenteritis (inflammation of the stomach and intestines), dental pain

Nervous System/Psychiatric:

Dizziness, headache

Respiratory System Disorders:

Nasal congestion, cough, influenza

Skin/Skin Appendages Disorder:

Rash

Pediatric Patients 6 to 14 Years of Age

Pharyngitis (inflammation of the back of the throat), influenza, fever, sinusitis (inflammation of the sinuses), nausea, diarrhea, dyspepsia, otitis (inflammation of the ear), viral infection, and laryngitis (inflammation of the voice box).

Pediatric Patients 2 to 5 Years of Age

Fever, cough, abdominal pain, diarrhea, headache, rhinorrhea (runny nose), sinusitis, otitis, influenza, rash, ear pain, gastroenteritis, eczema, urticaria (red, raised, itchy rash), Chicken pox, pneumonia (inflammation of the tissue in lungs), dermatitis (inflammation of the skin), and conjunctivitis (inflammation or infection of the outer membrane of the eyeball and the inner eyelid).

Pediatric Patients 6 to 23 Months of Age with Asthma

Upper respiratory infection, wheezing; otitis media; pharyngitis, tonsillitis (an inflammation of the two oval-shaped pads of tissue at the back of the throat), cough, and rhinitis.

Seasonal Allergic Rhinitis

Adults and Adolescents 15 Years of Age and Older

Upper respiratory infection and somnolence.

Pediatric Patients 2 to 14 Years of Age
Headache, otitis media, pharyngitis, and upper respiratory infection.

Perennial Allergic Rhinitis

Adults and adolescents 15 Years of Age and Older

Sinusitis, upper respiratory infection, sinus headache, cough, epistaxis (bleeding from the nose), increased ALT (liver enzyme), and somnolence.

Tell your healthcare provider right away if you notice any of the following behavior and mood-related changes: Obsessive-compulsive symptoms

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website <http://npra.moh.gov.my> [Public→Reporting side effects to medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Montexin* Storage

Keep out of the reach and sight of children.

Store below 30°C.

Protect from moisture and light.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Montexin Chewable Tablets 4 mg is a pink oval tablet, a ST/025 is scored on one side.

Montexin Chewable Tablets 5 mg is a pink round tablet, a ST/027 is scored on one side.

Ingredients

Active ingredient

Montexin Chewable Tablets 4 mg:

Montelukast Sodium 4.2 mg
(equivalent to Montelukast 4.0 mg)

Montexin Chewable Tablets 5 mg:

Montelukast Sodium 5.2 mg
(equivalent to Montelukast 5.0 mg)

Inactive ingredients

Aspartame, Hydroxypropyl Cellulose, Iron Oxide Red, Mannitol, Croscarmellose Sodium, Purified Water, 95% Alcohol, Strawberry micron, Microcrystalline Cellulose and Magnesium Stearate.

MAL number:

Montexin Chewable Tablets 4 mg
MAL10053672AZ

Montexin Chewable Tablets 5 mg:
MAL10053673AZ

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Montelukast (4mg, 5mg)

Manufacturer

Taiwan Biotech Co., Ltd.
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Taiwan, R.O.C.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
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