

XEPA ALTRA

Montelukast Sodium Chewable Tablets (4mg, 5mg)

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What XEPA ALTRA is used for

Your doctor has prescribed XEPA ALTRA (montelukast sodium) to treat:

- Asthma, including preventing your asthma symptoms during the day and night. XEPA ALTRA also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

What is asthma?

Asthma is a chronic lung disease. It cannot be cured – only controlled.

Characteristics of asthma include:

- Narrowed airways causing breathing to become difficult. This narrowing worsens and improves in response to various conditions.
- Inflamed airways; that is, the lining of airways become swollen.
- Sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.
- Symptoms of asthma include: Coughing, wheezing, and chest tightness. Not all people with asthma wheeze. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction (EIB) occurs when exercise triggers symptoms of asthma.

How do I know if I have asthma?

Your doctor will determine if you have asthma based on your symptoms and/or on how well you are able to move air out of

your lungs. Your doctor may use a device called a peak flow meter or a spirometer to test your lung function.

Treatment can control asthma. It is important to treat even mild symptoms of asthma so that you can prevent them from getting worse.

How should asthma be treated?

To help prevent asthma symptoms and improve your breathing you will have to work closely with your doctor to:

Plan ways to avoid or reduce contact with conditions that may trigger an asthma episode (for example, smoking including second-hand smoke, house dust mites, cockroaches, molds, pollen, animal dander, changes in weather and temperature, and infections in the upper airway (such as colds).

Develop a treatment plan that best controls your asthma.

Why is compliance (taking my medicine as prescribed) important?

Taking your medicine as your doctor or health care provider instructs may help reduce the severity of your asthma and the frequency of your asthma attacks.

What is allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as airborne pollens from trees, grasses, and weeds.
- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such as dust mites, animal dander, and/or mold spores.
- The daytime and nighttime symptoms of allergic rhinitis typically may include:
 - stuffy, runny, itchy nose
 - sneezing
 - watery, swollen, red, itchy eyes.

How XEPA ALTRA works

XEPA ALTRA is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Before you use XEPA ALTRA

When you must not use it

Do not take this medicine if you or your child are allergic (hypersensitivity) to the montelukast or any other ingredients in this medicine.

Before you start to use it

Tell your doctor (or health care provider) about any medical problems or allergies you or your child has now or has had.

Safety and effectiveness of XEPA ALTRA in children less than 12 months old have not been established.

Studies have shown that XEPA ALTRA does not affect the growth rate of children.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking XEPA ALTRA.

Use in breast-feeding

It is not known if XEPA ALTRA is excreted in breast milk. You should consult your doctor before taking XEPA ALTRA if you are breast-feeding or intend to breast-feed.

Taking other medicines

In general, XEPA ALTRA does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how XEPA ALTRA works, or XEPA ALTRA may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child is using or plan to use, including those obtained without a prescription.

Can I drive or operate machinery while using XEPA ALTRA?

XEPA ALTRA is not expected to affect your ability to drive a car or operate machinery.

How to use XEPA ALTRA

How much to use

Take XEPA ALTRA once a day with or without food, as your doctor has prescribed.

- The dose for children 6 to 14 years old for the treatment of asthma and/or allergic rhinitis is one 5-mg chewable tablet daily.
- The dose for children 2 to 5 years old for the treatment of asthma and/or allergic rhinitis is one 4-mg chewable tablet daily.

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When to use it

For patients with asthma, take XEPA ALTRA once a day in the evening.

For patients with allergic rhinitis, take XEPA ALTRA once a day as prescribed by your doctor.

How long to use it

It is important to continue taking XEPA ALTRA for as long as your doctor prescribes it in order to maintain control of your or your child's asthma.

XEPA ALTRA can treat your or your child's asthma only if you or your child continues to take it.

If you forget to use it

Try to take XEPA ALTRA as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet or packet once daily.

If you use too much (overdose)

Contact your doctor immediately.

While you are using it

Things you must do

It is important that you or your child continue taking XEPA ALTRA daily as prescribed by your doctor, even when you or your child has no symptoms or if you or your child has an asthma attack.

If your or your child's asthma symptoms get worse, you should contact your doctor immediately.

XEPA ALTRA is not for the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.

Behavior and mood-related changes have been reported in patients taking XEPA ALTRA. If you or your child experiences these changes while taking XEPA ALTRA (see "Side effects"), tell your doctor.

Things you must not do

If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg chewable tablets, do not take half a 10 mg tablet in its place.

The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.

Do not take XEPA ALTRA to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.

Remember that your doctor has prescribed this medicine only for you or your child. Never give it to anyone else.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. XEPA ALTRA is generally well-tolerated. In studies, the most common side effects reported were abdominal pain, headache, thirst, diarrhea, hyperactivity, asthma, scaly and itchy skin, and rash. These were usually mild and occurred as often in patients treated with montelukast or placebo (a pill containing no medication). Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency, low blood platelet count
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression, disorientation, disturbance in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal thoughts and actions, tremor, uncontrolled muscle movements]
- dizziness, drowsiness, pins and needles/numbness, very rarely seizure
- palpitations
- nose bleed; swelling (inflammation) of the lungs
- diarrhea, dyspepsia, nausea, vomiting
- hepatitis
- bruising, severe skin reactions (erythema multiforme) that may occur without warning
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- weakness/tiredness
- swelling
- fever

Tell your doctor or pharmacist if you or your child develops any unusual symptom, or if any known symptom continues or worsens.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

How can I learn more about XEPA ALTRA and the condition for which it was prescribed?

You may obtain further information from your physician or pharmacist, who have more detailed information about XEPA ALTRA and your condition.

Storage and Disposal of XEPA ALTRA

Storage

Store below 30°C.

Protect from light and moisture.

Keep out of the reach of the children.

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

XEPA ALTRA Chewable Tablets 5mg

Mottled pink, round tablet with 'crown' logo on one side and plain on the other side.

XEPA ALTRA Chewable Tablets 4mg

Mottled pink, round tablet with 'Z' logo on one side and plain on the other side.

Ingredients

XEPA ALTRA Chewable Tablets 5mg

- Active ingredient
Montelukast Sodium
- Inactive ingredients
Mannitol, Microcrystalline Cellulose, Croscarmellose Sodium, Hydroxypropyl Cellulose, Saccharin Sodium, Magnesium Stearate, Strawberry Flavour, Colour, Pigment Red.

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XEPA ALTRA Chewable Tablets 4mg

- Active ingredient
Montelukast Sodium
- Inactive ingredients
Mannitol, Microcrystalline Cellulose,
Croscarmellose Sodium,
Hydroxypropyl Cellulose, Saccharin
Sodium, Magnesium Stearate,
Strawberry Flavour, Colour, Pigment
Red.

MAL Number

XEPA ALTRA Chewable Tablets 5mg:

MALxxxxxxxAZ

XEPA ALTRA Chewable Tablets 4mg:

MALxxxxxxxAZ

Manufacturer and Product

Registration Holder (in Malaysia)

Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.
1-5 Cheng Industrial Estate,
75250 Melaka,
Malaysia.

Date of Revision

15/06/2026

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