

WARNING: SERIOUS NEUROPSYCHIATRIC EVENTS

See Warning and precaution for complete boxed warning.

For all uses of this drug:

- If changes in behavior are observed, or if new NEUROPSYCHIATRIC symptoms or suicidal thoughts and/or behavior occur, discontinue Broncast and contact a healthcare provider immediately.

For allergic reasons:

- This drug must only be used when other drugs cannot be used or have not worked. If you have questions, talk with the doctor.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What **Broncast Pediatric 5 mg chewable tablets** is and what it is used for
2. What you need to know before you take **Broncast Pediatric 5 mg chewable tablets**
3. How to take **Broncast Pediatric 5 mg chewable tablets**
4. Possible side effects
5. How to store **Broncast Pediatric 5 mg chewable tablets**
6. Further information

1. What Broncast Pediatric 5 mg chewable tablets is and what it is used for

What Broncast Pediatric 5 mg chewable tablets is

Broncast Pediatric 5 mg chewable tablets called ('Broncast Pediatric 5 mg' in this leaflet), is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Broncast Pediatric 5 mg works

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Broncast Pediatric 5 mg improves asthma symptoms and helps control asthma.

When Broncast Pediatric 5 mg should be used

Your doctor has prescribed Broncast Pediatric 5 mg to treat asthma, preventing your asthma symptoms during the day and night.

- Broncast Pediatric 5 mg is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
 - Broncast Pediatric 5 mg may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
 - Broncast Pediatric 5 mg also helps prevent the narrowing of airways triggered by exercise.
 - In those asthmatic patients in whom Broncast Pediatric 5 mg is indicated in asthma, Broncast Pediatric 5 mg can also provide symptomatic relief of seasonal allergic rhinitis.
- Your doctor will determine how Broncast Pediatric 5 mg should be used depending on the symptoms and severity of your or your child's asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
 - sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
 - swelling (inflammation) in the lining of the airways.
- Symptoms of asthma include: Coughing, wheezing, and chest tightness.

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. Before you take Broncast Pediatric 5 mg

Tell your doctor about any medical problems or allergies you or your child has now or has had.

Do not take Broncast Pediatric 5 mg

if you or your child is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before you or your child take Broncast Pediatric 5 mg.

If you or your child's asthma or breathing gets worse, tell your doctor immediately.

Oral Broncast Pediatric 5 mg is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. 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. Broncast Pediatric 5 mg should not be used instead of other asthma medications your doctor has prescribed for you or your child.

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 or your child 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.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with Broncast Pediatric 5 mg (see section 4). If you or your child develop such symptoms while taking Broncast Pediatric 5 mg, you should consult your doctor.

Children and adolescents

Do not give this medicine to children less than 6 years of age.

There are different form(s) of this medicine available for pediatric patients under 18 years of age based on age range.

Other medicines and Broncast Pediatric 5 mg

Tell your doctor or pharmacist if you or your child are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Broncast Pediatric 5 mg works, or Broncast Pediatric 5 mg may affect how other medicines work.

Tell your doctor if you or your child is taking the following medicines before starting Broncast Pediatric 5 mg:

phenobarbital (used for treatment of epilepsy)

phenytoin (used for treatment of epilepsy)

rifampicin (used to treat tuberculosis and some other infections)

Broncast Pediatric 5 mg with food and drink

Broncast Pediatric 5 mg 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Broncast Pediatric 5 mg.

Pregnancy

Your doctor will assess whether you can take Broncast Pediatric 5 mg during this time.

Breast-feeding

It is not known if Broncast Pediatric 5 mg appears in breast milk. You should consult your doctor before taking Broncast Pediatric 5 mg if you are breast-feeding or intend to breast-feed.

Driving and using machines

Broncast Pediatric 5 mg 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 with Broncast Pediatric 5 mg may affect some patients' ability to drive or operate machinery.

Broncast Pediatric 5 mg chewable tablets contain aspartame, a source of phenylalanine and sodium

If you or your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should note that Montelukast Chewable Tablets contain aspartame, which is a source of phenylalanine. The phenylalanine in the tablets may be harmful to people with phenylketonuria. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Broncast Pediatric 5 mg

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You or your child should take only one chewable tablet of Broncast Pediatric 5 mg once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

Broncast Pediatric 5 mg chewable tablets Montelukast 5 mg

For children 6 to 14 years of age:

The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.

If you or your child are taking Broncast Pediatric 5 mg, be sure that you or your child do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Broncast Pediatric 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If you or your child takes more Broncast Pediatric 5 mg more than you should

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.

If you forget to take Broncast Pediatric 5 mg or give Broncast Pediatric 5 mg to your child

Try to take Broncast Pediatric 5 mg as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you or your child stops taking Broncast Pediatric 5 mg

Broncast Pediatric 5 mg can treat you or your child's asthma only if you or your child continues to take it.

It is important to continue taking Broncast Pediatric 5 mg for as long as your doctor prescribes. It will help control you or your child's asthma.

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

4. Possible side effects

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

In clinical studies with **Broncast Pediatric 5 mg chewable tablets**, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Broncast Pediatric 5 mg were:

- headache

Additionally, the following side effect was reported in clinical studies with Broncast 10 mg film-coated tablets:

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with Broncast than placebo (a pill containing no medication).

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects, which may be serious, and for which you or your child may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression

- seizure

Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor

- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- 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) (see section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs

- severe skin reactions (erythema multiforme) that may occur without warning

- inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting

- rash

- fever

- elevated liver enzymes

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed

- dry mouth, indigestion

- bruising, itching, hives

- joint or muscle pain, muscle cramps

- bedwetting in children

- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)

- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

5. How to store Broncast Pediatric 5 mg

- Keep this medicine out of the sight and reach of children.

- Store below 30°C.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment.

6. Further information

What Broncast Pediatric 5 mg contains

• The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 5 mg of montelukast.

• The other ingredients are: Mannitol, Microcrystalline cellulose, hydroxypropylcellulose, Crosscarmellose sodium, Red Iron Oxide, Bubble Gum Flavor, Aspartame, Colloidal Silicon Dioxide and Magnesium Stearate

What Broncast Pediatric 5 mg looks like and contents of the pack

Broncast Pediatric 5 mg chewable tablets are pink to reddish, round, biconvex with, Blisters (unit doses), in packages of 28 tablets.

Manufacturer & Marketing Authorisation Holder:

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To report any side effect(s):

• **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC) • Fax: +966-11-205-7662 • SFDA call center: 19999 • Toll free phone: 8002490000 • E-mail: npc.drug@sfd.gov.sa • Website: https://ade.sfd.gov.sa
• Other GCC States:
Please contact the relevant competent authority.
THIS IS A MEDICAMENT - 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 the experts in medicines, their 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 all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists

