

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 10 mg film-coated tablet is and what it is used for
 2. What you need to know before you take Broncast 10 mg film-coated tablet
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1. What Broncast 10 mg film-coated tablet is and what it is used for

What Broncast 10 mg film-coated tablet is
Broncast 10 mg film-coated tablet called ('Broncast' in this leaflet), is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Broncast works
Leukotrienes cause narrowing and swelling of airways in the lungs and cause allergy symptoms. By blocking leukotrienes, Broncast improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When Broncast should be used
Your doctor has prescribed Broncast to treat asthma, preventing your asthma symptoms during the day and night.
• Broncast is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
• Broncast also helps prevent the narrowing of airways triggered by exercise.
• In those asthmatic patients in whom Broncast is indicated in asthma, Broncast can also provide symptomatic relief of seasonal allergic rhinitis.
Your doctor will determine how Broncast should be used depending on the symptoms and severity of your 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 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. What you need to know before you take Broncast 10 mg film-coated tablet?

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

Do not take Broncast
• if you are 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 taking Broncast.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Broncast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. 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 should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a 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 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.

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

Children and adolescents
Do not give this medicine to children less than 15 years of age.

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

Other medicines and Broncast
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.
Some medicines may affect how Broncast works, or Broncast may affect how other medicines work.
Tell your doctor if you are taking the following medicines before starting Broncast:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma)

Broncast with food and drink
Broncast 10 mg film-coated tablet may be taken with or without 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.

Pregnancy
Your doctor will assess whether you can take Broncast during this time.

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

Driving and using machines
Broncast 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 may affect some patients' ability to drive or operate machinery.

Broncast 10 mg film-coated tablets contain lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Broncast 10 mg film-coated tablet

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

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

For adults and adolescents 15 years of age and older:
The recommended dose is one 10 mg tablet to be taken daily in the evening.

Broncast 10mg Film coated tablet

Montelukast

If you are taking Broncast, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.
You can take Broncast 10 mg with or without food.

If you use more Broncast 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 use Broncast
Try to take Broncast as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.
Do not take a double dose to make up for a forgotten dose.

If you stop using Broncast
Broncast can treat your asthma only if you continue to take it.
It is important to continue taking Broncast for as long as your doctor prescribes. It will help control your 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 montelukast film-coated tablet, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Broncast were:

- abdominal pain
- headache

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 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

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

- 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 10 mg film-coated tablet

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Store in the original package in order to protect from light and moisture.
- 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 contains
• The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.

• The other ingredients are: Lactose, Crosscarmellose sodium, Colloidal silicone dioxide, Mg-stearate, Hypromellose 606, Titanium dioxide, Yellow Iron Oxide and Red Iron Oxide.

What Broncast looks like and contents of the pack
Broncast 10 mg film-coated tablets are Paige, compact, biconvex, 8 x 8 mm square curved edges film-coated tablets embossed with MF in one side with blisters in packages of: 28 tablets.

Manufacturer & Marketing Authorisation Holder:
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Tel: +966 (11) 2653948 - 2653427
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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: 800249000
- E-mail: npc.drug@sfdagov.sa
- Website: <https://ade.sfdagov.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