Package leaflet: Information for the user

Actamone 4 mg chewable tablets

montelukast

Read all of this leaflet carefully before you give this medicine to your child because it contains important information.
- 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 Actamone is and what it is used for
2. What you need to know before your child takes Actamone
3. How to take Actamone
4. Possible side effects
5. How to store Actamone
6. Contents of the pack and other information

1. What Actamone is and what it is used for

What Actamone is
Actamone is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Actamone works
Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Actamone improves asthma symptoms and helps control asthma.

When Actamone should be used
Your doctor has prescribed Actamone to treat your child's asthma, preventing asthma symptoms during the day and night.

- Actamone is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Actamone may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- Actamone also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Actamone should be used depending on the symptoms and severity of 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.

2. What you need to know before your child takes Actamone

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

Do not give Actamone to your child:

- if he/she 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 give Actamone to your child:
- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Actamone is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child takes all asthma medications prescribed by your doctor. Actamone should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops 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.
- 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 his/her asthma worse.

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If your child develops such symptoms while taking montelukast, you should contact your doctor.

Children and adolescents

Do not give this medicine to children less than 2 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 Actamone

Tell your doctor or pharmacist if your child is taking or has recently been given or might be given any other medicines including those obtained without a prescription.

Some medicines may affect how Actamone works, or Actamone may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Actamone:
- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

Actamone with food and drink

Actamone 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

This subsection is not applicable for the Actamone 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for the Actamone 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Actamone 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 Actamone may affect some patients' ability to drive or operate machinery.

Actamone chewable tablets contain aspartame, lactose and sodium:

This medicine contains 1.2 mg aspartame in each 4 mg chewable tablet which is equivalent to 0.5 mg/100 mg. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Actamone chewable tablets contain lactose. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before you give this medicinal product to your child.

This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.

3. How to take Actamone

- Always have your child take this medicine exactly as your doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.
- This medicine is to be given to a child under adult supervision. For children who have problems consuming a chewable tablet, an oral granule formulation is available.
- Your child should take only one chewable tablet of Actamone once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 2 to 5 years of age**:**
The recommended dose is one 4 mg chewable tablet daily to be taken in the evening.

If your child is taking Actamone, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.
The tablets are to be chewed before swallowing.

Actamone 4 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 your child takes more Actamone than he/she should

Contact your child's 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 give Actamone to your child

Try to give Actamone as prescribed. However, if your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

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

If your child stops taking Actamone

Actamone can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Actamone for as long as your doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's 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 Actamone 4 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Actamone were:
- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with Actamone 10 mg film- coated tablets and 5 mg chewable tablets:
- headache

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

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects with your child, which may be serious, and for which 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

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

Reporting of side effects
If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to ADR Reporting www.medicinesauthority.gov.mt/adrportal.

5. How to store Actamone

- Keep this medicine out of the sight and reach of children.
- Do not use Actamonethis medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light and moisture.
- Do not store above 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Actamone contains

- The active substance is montelukast. Each chewable tablet contains montelukast sodium which corresponds to 4 mg of montelukast.

- The other ingredients (excipients) are: microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, lactose monohydrate, iron oxide red (E172), mannitol, silarom cherry flavour (nature-identical flavouring substances, flavouring preparations, natural flavouring substances, maltodextrin (potato), gum arabic (acacia) (E414), triacetin (E1518), ethyl maltol, maltol, alpha-tocopherol (E307)), aspartame (E951), magnesium stearate.

What Actamone looks like and contents of the pack

Actamone 4 mg chewable tablets are pink, mottled, oval, biconvex tablets, size 7.8 mm x11 mm, with M4 engraved on one side.

Blisters in packages of:
7, 10, 14, 28, 30, 56, 60, 98, 100 chewable tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sigillata Limited

Landscape House
Baldonnell Business Park
Baldonnell,
DUBLIN,
D22 P3K7,
Ireland

Manufacturer
Actavis Ltd.
BLB016
Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Malta: Actamone

This leaflet was last revised in June 2025.