Package leaflet: Information for the user

Actamone 5 mg chewable tablets
For children 6 to 14 years of age

montelukast

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you or your child.
- 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 or 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 or your child's.
- If you or your child 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 Actamone is and what it is used for
2. What you need to know before you or your child take Actamone
3. How to take Actamone
4. Possible side effects
5. How to store Actamone
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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 asthma, preventing your asthma symptoms during the day and night.

- Actamone 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.
- Actamone 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.
- Actamone also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Actamone 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.

2. What you need to know before you or your child take Actamone

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

Do not take Actamone

- 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 Actamone:
- If you or 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 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. Actamone 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.

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 6 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 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 Actamone works, or Actamone may affect how other medicines work.
Tell your doctor if you or 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 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 breast-feeding

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 this medicine.

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

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

Driving and using machines

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 1.5 mg aspartame in each 5 mg chewable tablet which is equivalent to 0.5 mg/100 mg. Aspartame is a source of phenylalanine. It may be harmful if you or your child have 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 you or your child have an intolerance to some sugars, contact your doctor before this medicinal product is taken.

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 take 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 Actamone 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.

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 Actamone, 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.

Actamone 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 Actamone 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 Actamone or give Actamone to your child

Try to take Actamone 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 Actamone

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

It is important to continue taking Actamone 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 montelukast 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- headache

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

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with montelukast 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

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 you or your child get 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 Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Actamone

- Keep this medicine out of the sight and reach of children.
- Do not use this 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 5 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, alphatocopherol (E307)), aspartame (E951), magnesium stearate.

What Actamone looks like and contents of the pack

5 mg Actamone chewable tablets are pink, mottled, round, biconvex tablets, diameter 9.5 mm, with M5 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 06/2025.