

450 mm

Montelukast 10 mg film-coated tablets
Montelukast

- 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.

1. What Montelukast is and what it is used for
2. What you need to know before you take Montelukast
3. How to take Montelukast
4. Possible side effects
5. How to store Montelukast
6. Contents of the pack and other information

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes.

- Montelukast 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.
- Montelukast also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast is indicated in asthma, Montelukast can also provide symptomatic relief of seasonal allergic rhinitis.

- 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.

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 you develop such symptoms while taking montelukast, you should contact your doctor.

- 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).

- The recommended dose is only one tablet of Montelukast once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- To be taken by mouth.

This product is not suitable for children and adolescents under 15 years of age for whom alternative products available in lower



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- abdominal pain
- headache

Uncommon (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

- increased bleeding tendency
- tremor
- palpitations

- 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
- hepatitis (inflammation of the liver)
- severe skin reactions (erythema multiforme) that may occur without warning

- upper respiratory infection

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleep walking,
- irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nose bleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

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

- tender red lumps under the skin most commonly on your shins (erythema nodosum) behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

Do not store above 30 °C.

Store in the original package in order to protect from light and moisture.

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.

- The active substance is montelukast. Each film-coated tablet contains montelukast sodium which corresponds to 10 mg of montelukast.
- The other ingredients are: cellulose, microcrystalline (E460), lactose monohydrate, hydroxypropylcellulose, low substituted (E463), croscarmellose sodium (E468), magnesium stearate (E572).

Film coating: hypromellose, type 2910 (E464), hydroxypropylcellulose (E463), titanium dioxide (E171), carnauba wax (E903), iron oxide yellow (E172), iron oxide red (E172).

Montelukast 10mg film-coated tablets are beige coloured, rounded square, film coated, biconvex tablets, plain on both sides.

Packaged in OPA-Al-PVC/Al blister in following pack sizes 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140 and 200 tablets.

Not all pack sizes may be marketed.

Rivopharm UK Ltd
100 Bishopsgate
London
EC2N 4AG
United Kingdom

Rivopharm UK Ltd
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United Kingdom

United Kingdom
The Netherlands
Germany

Montelukast 10 mg film-coated tablets
Montelukast Indoco 10 mg filmomhulde tabletten
Montelukast Indoco 10 mg Filmtabletten

This leaflet was last revised in November 2024



Rivopharm



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