

- depression
- disorientation (confusion)
- feeling anxious
- hallucinations (seeing or hearing things that are not really there)
- irritability
- memory problems
- restlessness
- sleep walking
- suicidal thoughts and actions (including suicide)
- tremor
- trouble sleeping
- uncontrolled muscle movements

• **Increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis).** Rarely, this can happen in people with asthma who take montelukast sodium. This sometimes happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered.

Tell your healthcare provider right away if you get one or more of these symptoms:

- a feeling of pins and needles or numbness of arms or legs
- a flu-like illness
- rash
- severe inflammation (pain and swelling) of the sinuses (sinusitis)

The most common side effects with montelukast sodium tablets and/or chewable tablets include:

- upper respiratory infection
- fever
- headache
- sore throat
- cough
- stomach pain
- diarrhea
- earache or ear infection
- flu
- runny nose
- sinus infection

Other side effects with montelukast sodium tablets and/or chewable tablets include:

- increased bleeding tendency, low blood platelet count
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives and itching]
- dizziness, drowsiness, pins and needles/numbness, seizures (convulsions or fits)
- palpitations
- nose bleed, stuffy nose, swelling (inflammation) of the lungs
- heartburn, indigestion, inflammation of the pancreas, nausea, stomach or intestinal upset, vomiting
- hepatitis
- bruising, rash, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis) that may occur without warning
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- tiredness, swelling

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of montelukast sodium tablets and/or chewable tablets. For more information ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store montelukast sodium tablets and/or chewable tablets?

- Store montelukast sodium tablets and/or chewable tablets at 59°F to 86°F (15°C to 30°C).
- Keep montelukast sodium tablets and/or chewable tablets in the container it comes in.
- Keep montelukast sodium tablets and/or chewable tablets in a dry place and away from light.

General Information about the safe and effective use of montelukast sodium tablets and/or chewable tablets

Medicines are sometimes prescribed for purposes other than those mentioned in Patient Information Leaflets. Do not use montelukast sodium tablets and/or chewable tablets for a condition for which it was not prescribed. Do not give montelukast sodium tablets and/or chewable tablets to other people even if they have the same symptoms you have. It may harm them. **Keep montelukast sodium tablets and/or chewable tablets and all medicines out of the reach of children.**

This leaflet summarizes information about montelukast sodium tablets and/or chewable tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about montelukast sodium tablets and/or chewable tablets that is written for health professionals. For more information, call **Par Pharmaceutical at 1-800-828-9393.**

What are the ingredients in montelukast sodium tablets and chewable tablets?

Active ingredient: montelukast sodium

Inactive ingredients:

- **10-mg tablet:** croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and silicified microcrystalline cellulose. The film coating contains: hydroxypropyl cellulose, hypromellose, red ferric oxide, titanium dioxide and yellow ferric oxide.
- **4-mg and 5-mg chewable tablets:** aspartame, croscarmellose sodium, flavor black cherry, hydroxypropyl cellulose, magnesium stearate, mannitol, red ferric oxide, and silicified microcrystalline cellulose.

People with Phenylketonuria: montelukast sodium 4-mg chewable tablets contain 1.2 mg of phenylalanine, and montelukast sodium 5-mg chewable tablets contain 1.5 mg of phenylalanine.

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Par Pharmaceutical
Chestnut Ridge, NY 10977

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R3

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