TABLETS AND somnambulism, suicidal thinking and behavior (including suicide), and tremor. The clinical details rhinitis have not been established.

patients 6 years of age and older.

1  INDICATIONS AND USAGE

4 CONTRAINDICATIONS

sometimes associated with the reduction of oral corticosteroid therapy. Physicians should be alert.

Relief of symptoms of allergic rhinitis (AR): seasonal allergic rhinitis (SAR) in patients 2 years of age and older, and perennial

HIGHLIGHTS OF PRESCRIBING INFORMATION

1. 2 Exercise-Induced Bronchoconstriction (EIB)

were treated with montelukast sodium for at least 3 months, 230 for 6 months or longer, and 63

Montelukast sodium has been evaluated for safety in 573 pediatric patients 2 to 5 years of age

profile did not significantly change.

The frequency of less common adverse events was comparable between montelukast sodium

Musculoskeletal and connective tissue disorders: arthralgia, myalgia including muscle cramps.

Gastrointestinal disorders: diarrhea, dyspepsia, nausea, pancreatitis, vomiting.

Nervous system disorders: drowsiness, paraesthesia/hypoesthesia, seizures.

suicide), and tremor

disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability,

The comparative plus montelukast sodium administered as its 4-mg tablets showed 68 to 80% lower plasma levels than the

Developed in more than 3800 patients. Adverse reactions rated 2% or greater in patients treated with montelukast sodium 4-mg tablets and placebo: headache, rhinitis, and nasopharyngitis were 2.9% and 2.2% for montelukast sodium and placebo, respectively. In pediatric patients treated with montelukast sodium 4-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively. In patients treated with montelukast sodium 4-mg tablets and placebo, headache, rhinitis, and nasopharyngitis were 2.8% and 2.3% for montelukast sodium and placebo, respectively.

In clinical studies of montelukast sodium 5-mg chewable tablets, 2.6% (2.6 mg) of patients experienced headache, nausea, and vomiting (2.0 mg) in patients treated with montelukast sodium 4-mg tablets and placebo, respectively. In pediatric patients treated with montelukast sodium 4-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.

In patients treated with montelukast sodium 10-mg tablets and placebo, headache, rhinitis, and nasopharyngitis were 2.6% and 2.3% for montelukast sodium and placebo, respectively. In pediatric patients treated with montelukast sodium 10-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.

In patients treated with montelukast sodium 10-mg tablets and placebo, headache, rhinitis, and nasopharyngitis were 2.8% and 2.3% for montelukast sodium and placebo, respectively.

In pediatric patients treated with montelukast sodium 10-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.

In patients treated with montelukast sodium 10-mg tablets and placebo, headache, rhinitis, and nasopharyngitis were 3.0% and 2.3% for montelukast sodium and placebo, respectively.

In pediatric patients treated with montelukast sodium 10-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.

In patients treated with montelukast sodium 10-mg tablets and placebo, headache, rhinitis, and nasopharyngitis were 2.6% and 2.3% for montelukast sodium and placebo, respectively.

In pediatric patients treated with montelukast sodium 10-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.

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In pediatric patients treated with montelukast sodium 10-mg tablets, headache, rhinitis, and nasopharyngitis were 2.6% and 2.5% for montelukast sodium and placebo, respectively.
Montelukast at a dose of 10 mg once daily showed a pharmacological effect in the treatment of asthma. The data from the 599 patients who participated in the 2-month study showed that montelukast sodium tablets and/or chewable tablets were effective in the treatment of asthma.

### Endpoint N Baseline Mean Change

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>N Baseline</th>
<th>Mean Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>symptom scores</td>
<td>5.6</td>
<td>-0.2</td>
</tr>
<tr>
<td>&quot;as-needed&quot; treatment</td>
<td>2.3</td>
<td>-0.5</td>
</tr>
<tr>
<td>forced expiratory volume in 1 second (FEV1)</td>
<td>1.2</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### Safety and Tolerability

Montelukast sodium tablets and/or chewable tablets were generally well tolerated, with no major differences in the incidence of adverse events compared to placebo. The most common side effects reported were headache, nasopharyngitis, and upper respiratory tract infections. Montelukast sodium tablets and/or chewable tablets do not contain a source of phenylalanine.

### Warnings and Precautions

- Montelukast sodium tablets and/or chewable tablets are not recommended for use in children under 2 years of age and in pregnant or breastfeeding women.
- Montelukast sodium tablets and/or chewable tablets should be taken with food to reduce the risk of gastrointestinal side effects.
- Montelukast sodium tablets and/or chewable tablets should be stored in a cool, dry place and away from moisture and light.

### What are the possible side effects of montelukast sodium tablets and/or chewable tablets?

Montelukast sodium may cause side effects such as:

- nausea, vomiting, or diarrhea
- dry mouth
- skin rash
- heartburn
- abdominal pain
- headache
- dizziness
- shortness of breath
- fast or irregular heartbeat
- swelling in the hands and feet

If any of these side effects persist or worsen, or if you are experiencing any other side effects, please consult your healthcare provider.

### Instructions for Use

1. Montelukast sodium tablets and/or chewable tablets should be taken as directed by your healthcare provider.
2. Take montelukast sodium tablets and/or chewable tablets every day, even if you feel well.
3. Do not share montelukast sodium tablets and/or chewable tablets with others, as they are intended for use by specific individuals.
4. Montelukast sodium tablets and/or chewable tablets should be taken with food to reduce the risk of gastrointestinal side effects.

### Additional Information

- Montelukast sodium tablets and/or chewable tablets are available in 4-mg, 5-mg, and 10-mg strengths.
- Montelukast sodium tablets and/or chewable tablets are not recommended for use in children under 2 years of age.
- Montelukast sodium tablets and/or chewable tablets are not recommended for use in pregnant or breastfeeding women.

### References


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**Note:** The above information is for educational purposes only and should not be used as a substitute for professional medical advice.