**Composition**
1 tablet contains 8 mg
5 ml syrup contain 4 mg
N-cyclohexyl-N-methyl-(2-amino-3,5-dibromobenzyl) amine hydrochloride (= bromhexine hydrochloride)

**Excipients:**
Tablets: lactose, maize starch, magnesium stearate
Syrup 4 mg: maltitol liquid, sucralose, benzoic acid, cherry flavour, chocolate flavour, levomenthol.

**Pharmacological Properties**
Bromhexine is a synthetic derivative of the herbal active ingredient vasicine. Preclinically, it has been shown to increase the proportion of serous bronchial secretion. Bromhexine enhances mucus transport by reducing mucus viscosity and by activating the ciliated epithelium (mucociliary clearance). In clinical studies, bromhexine showed a secretolytic and secretomotor effect in the bronchial tract area, which facilitates expectoration and eases cough. Following the administration of bromhexine antibiotic concentrations (amoxicillin, erythromycin, oxytetracycline) in the sputum and bronchopulmonary secretions are increased.

**Indications**
Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport. It is indicated in the treatment of acute and chronic respiratory tract disorders associated with viscid mucus.

**Contraindications**
BISOLVON should not be used in patients known to be hypersensitive to bromhexine or other components of the formulation. In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to “Special warnings and precautions”) the use of the product is contraindicated.

**Special warnings and precautions**
For tablets:
This product contains 222 mg of Lactose per maximum recommended daily dose. Patients with rare hereditary problems of galactose intolerance e.g. galactosaemia should not take this medicine.

*For syrup:*
This product contains 7.5 g Maltitol liquid per maximum recommended daily dose. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

There have been very rare reports of severe skin lesions such as Stevens Johnson syndrome and Lyell’s syndrome in temporal association with the administration of mucolytic substances such as bromhexine. Mostly these could be explained by the severity of the underlying disease or concomitant medication. If new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with bromhexine discontinued as a precaution.

**Drug Interactions**
No clinically relevant unfavourable interactions with other medications have been reported.

**Pregnancy and Lactation**
Available preclinical studies as well as clinical experience to date have shown no evidence of ill-effects during pregnancy. Nonetheless, the usual precautions regarding the use of drugs during pregnancy, especially during the first trimester, should be observed. The drug is expected to enter breast milk and thus should be avoided during lactation.

**Side Effects**
BISOLVON is generally well tolerated. Diarrhoea, nausea, vomiting and other mild gastrointestinal side effects have been reported. Allergic reactions, including skin rashes, bronchospasm, angio-oedema, and anaphylaxis have also been reported.
Dosage and administration

Tablets 8 mg

<table>
<thead>
<tr>
<th>Group</th>
<th>Dosage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children over 12 years</td>
<td>8 mg (1 tablet)</td>
<td>3 times daily</td>
</tr>
<tr>
<td>Children 6 - 12 years:</td>
<td>4 mg (1/2 tablet)</td>
<td>3 times daily</td>
</tr>
<tr>
<td>Children 2 - 6 years:</td>
<td>4 mg (1/2 tablet)</td>
<td>2 times daily</td>
</tr>
</tbody>
</table>

Syrup 8 mg/5 ml (5 ml = 1 teaspoon)

<table>
<thead>
<tr>
<th>Group</th>
<th>Dosage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children over 12 years</td>
<td>5 ml (1 teasp.)</td>
<td>3 times daily</td>
</tr>
<tr>
<td>Children 6 - 12 years:</td>
<td>2.5 ml (1/2 teasp.)</td>
<td>3 times daily</td>
</tr>
</tbody>
</table>

At commencement of treatment, it may be necessary to increase the total daily dose up to 48 mg in adults. The syrup is sugar-free and therefore suitable for diabetics and small children.

NOTE: Patients being treated with BISOLVON should be notified of an expected increase in the flow of secretions.

Overdosage

No symptoms of overdosage have been reported in man to date. If they occur, symptomatic treatment should be provided.

Availability

Tablets 8 mg; Syrup 8 mg/5 ml

Storage instructions

Store in a safe place below 30°C. Store in a safe place out of the reach of children!