

bromsal[®] (Expectorant)



23400

Ref. No: B2123400/22.02

Salbutamol Sulphate / Bromhexine Hydrochloride / Guaifenesin / Menthol
Bronchodilator / Mucolytic / Expectorant

PRESENTATION:

bromsal[®] expectorant: Clear orange slightly viscous pleasantly flavoured syrup, free from any evidence of contamination.

Each 5mL contains:

Salbutamol Sulphate equivalent to Salbutamol	1mg
Bromhexine Hydrochloride	2mg
Guaifenesin	50mg
Menthol	0.5mg

CLINICAL PHARMACOLOGY:

Salbutamol is a direct-acting sympathomimetic with predominantly beta-adrenergic activity and a selective action on beta₂ receptors (a beta₂ agonist). This results in its bronchodilating action being more prominent than its effect on the heart.

Bromhexine is a mucolytic used in the treatment of respiratory disorders associated with productive cough.

Guaifenesin is reported to increase the volume and reduce the viscosity of tenacious sputum and is used as an expectorant.

Menthol is chiefly used to relieve symptoms of bronchitis, sinusitis, and similar conditions. For this purpose it may be used as an inhalation, usually with benzoin or eucalyptus oil, as pastilles, or as an ointment with camphor and eucalyptus oil for application to the chest or nostrils.

Pharmacokinetics:

Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first-pass metabolism in the liver and possibly in the gut wall; the main metabolite is an inactive sulfate conjugate. Salbutamol is rapidly excreted in the urine as metabolites and unchanged drug; there is some excretion in the faeces. Salbutamol does not appear to be metabolised in the lung, therefore its ultimate metabolism and excretion following inhalation depends upon the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. It has been suggested that the majority of an inhaled dose is swallowed and absorbed from the gut. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and undergoes extensive first-pass metabolism in the liver.

It is widely distributed to body tissues. About 85 to 90% of a dose is excreted in the urine mainly as metabolites. Bromhexine is highly bound to plasma proteins. It has a terminal elimination half-life of up to about 12 hours. Bromhexine crosses the blood-brain barrier and small amounts cross the placenta.

Guaifenesin is absorbed from the gastro-intestinal tract. It is metabolised and excreted in the urine.

After absorption, menthol is excreted in the urine and bile as a glucuronide.

USES:

bromsal[®] is used as a bronchodilator in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease. It also increases the volume and reduces the viscosity of tenacious sputum and is used as an expectorant for productive cough.

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DOSAGE AND ADMINISTRATION:

Adults: 10mL (2 spoonfuls) 3 times daily.

Children 6-12 years: 5mL - 10mL (1 -2 spoonfuls) 3 times daily.

Below 6 years: 5mL (1 spoonful) 3 times daily.

The above doses may have to be raised in some patients to get the desired effect.

CONTRA-INDICATIONS AND WARNINGS:

Precautions:

bromsal[®] Expectorant should be used with caution in patients of hyperthyroidism, diabetes mellitus, serious cardiovascular disorders, hypertension and peptic ulcers.

Adverse Effects:

These are generally mild and rare. Skeletal muscle tremor particularly of the hands, palpitations and muscle cramps are seen occasionally. Slight tachycardia, headache and peripheral vasodilation have been reported after large doses.

Pregnancy and Lactation:

The safety data in pregnancy and lactation has not been fully established. However the product should only be used in pregnancy when considered essential by the doctor.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)

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