

# ASMALIN EXPECTORANT

Each 5ml contains:-  
Terbutaline Sulphate 1.5mg  
Guaiphenesin 65.0mg

**Product Description:**  
A clear, colourless syrup with menthol flavour.

**Pharmacodynamics:**  
Terbutaline sulphate is a  $\beta$ -adrenergic receptor agonist which exerts a preferential effect on  $\beta_2$  adrenergic receptors such as those located in bronchial smooth muscle. It has been shown in controlled clinical studies to relieve bronchospasm in chronic obstructive pulmonary disease. Guaiphenesin is an expectorant which increases respiratory secretions (thereby thinning the mucus), possibly by stimulating the goblet cells.

**Pharmacokinetics:**  
Terbutaline is incompletely absorbed from the gastro-intestinal tract and is also subject to fairly extensive first-pass metabolism by sulphate and some glucuronide conjugation in the liver and possibly the gut wall. Following the administration of terbutaline, a clinically significant improvement in pulmonary function occurs at 60 - 120 minutes. The maximum effect usually occurs within 120 - 180 minutes. Terbutaline also produces a significant decrease in pulmonary airway resistance which persists for at least four hours. Significant bronchodilation has been demonstrated for periods up to 8 hours. Terbutaline is excreted in the urine partly as the inactive conjugates and partly as unchanged terbutaline. Guaiphenesin is readily absorbed from gastrointestinal tract, blood concentrations of 1.4 $\mu$ g per ml occurring 15 minutes after a dose of 600mg in 3 healthy fasting men. It is rapidly eliminated from the circulation, having a half-life of 1 hour and is not detectable after 8 hours.

**Indication:**  
It is indicated in conditions where both bronchodilation and expectoration effects are required such as in chronic bronchitis and emphysema.

**Recommended Dosage:**  
The usual oral dose for adults: One to two teaspoonful two to three times daily.  
A total dose of 15mg of terbutaline should not be exceeded in a 24-hour period.  
The usual oral dose for children age 7 to 15 years: One teaspoonful two times daily.  
A total dose of 7.5mg of terbutaline should not be exceeded in a 24-hour period.

**Route of Administration:** Oral

**Contraindications:**  
It is contraindicated in patients who have exhibited hypersensitivity to any of its ingredients or other sympathomimetics.

**Warnings and Precautions:**  
Tocolysis: Serious adverse reaction including death have been reported after administration of terbutaline/ salbutamol to women in labor. In the mother, these include increased heart rate, transient hyperglycaemia, hypokalaemia, cardiac arrhythmias, pulmonary oedema, and myocardial ischaemia. Increased fetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration.

Terbutaline sulphate should be used with caution in patient with diabetes, hypertension, hyperthyroidism, and a history of seizures. As with any other sympathomimetic bronchodilator agents, it should be administered cautiously to cardiac patients, especially those with associated

arrhythmias. The concomitant use of terbutaline with other sympathomimetics is not recommended since their combined effect on the cardiovascular system may be deleterious to the patients.

**Interactions with Other Medicaments:**  
 $\beta$ -blockers may inhibit bronchodilating effect. Other sympathomimetic bronchodilators or epinephrine should not be used concomitantly with terbutaline sulphate since their combined effect on the cardiovascular system may be deleterious to the patient. This recommendation does not preclude the judicious use of an aerosol bronchodilator of the adrenergic stimulant type in patients receiving Asmalin Expectorant. Such concomitant use, however, should be individualized and not given on a routine basis. If regular coadministration is required, alternative therapy should be considered. Terbutaline sulphate should be administered with caution in patients being treated with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants, since the action of terbutaline sulphate on the vascular system may be potentiated.  $\beta$ -adrenergic receptor blocking agents not only block the pulmonary effect of terbutaline but may produce severe asthmatic attacks in asthmatic patients. Therefore, patients requiring treatment for both bronchospastic disease and hypertension should be treated with medication other than  $\beta$ -adrenergic blocking agents for hypertension.

**Pregnancy and Lactation:**  
Although no teratogenic effects have been observed in animals or in patients, caution is recommended during the first trimester of pregnancy. Terbutaline sulphate has been taken by a large number of pregnant women and women of childbearing age without any reported increase of malformation frequency or other signs of disturbance of the reproductive process. Terbutaline sulphate passes over to maternal milk but the risk of influence on the child is unlikely with therapeutic doses.

**Side Effects:**  
Commonly observed side effects include nervousness and tremor. Other reported reaction include headache, increased heart rate, palpitations, drowsiness, nausea, vomiting, sweating and muscle cramp. These effects are generally transient in nature.

**Symptoms and Treatment of Overdose:**  
Excessive  $\beta$ -adrenergic stimulation may augment the signs and symptoms listed under Side Effects. Treat the alert patient by emptying the stomach by emesis, followed by gastric lavage. In the unconscious patient, secure the airway with a cuffed endotracheal tube before inducing lavage. Instillation of activated charcoal slurry may help reduce the absorption of terbutaline sulphate. Maintain adequate respiratory exchange. Provide cardiac and respiratory support as needed.

**Effects on Ability to Drive and Use Machine:**  
Asmalin Expectorant has no or negligible influence on the ability to drive and use machines.

**Storage Conditions:** Store at or below 30°C. Protect from light.

**Pack Sizes:** A bottle of 60ml, 100ml and 120ml.  
**Pack Sizes(export only):** A bottle of 3.6 litres and 3.8 litres.

**Shelf-life:** 3 years.

**FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.**

Manufacturer & Product Registration Holder:  
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