

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	ASTHAREN TABLETS (Salbutamol sulphate 4mg)
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Pack insert

ASTHAREN TABLETS

SALBUTAMOL TABLET BP 4MG

Composition:

Each uncoated tablet contains:

Salbutamol sulphate BP Equivalent to salbutamol 4 mg

Category: Antiasthmatics Drug

Clinical Pharmacology:

Salbutamol is a direct-acting sympathomimetic agent with a relatively selective action on beta₂-adrenoceptors. Its main clinical uses are in the management of reversible airways obstruction such as occurs in asthma and in delaying premature labour. It can be given by the pulmonary, oral, and Parenteral routes.

Adverse effects of Salbutamol are essentially those of adrenergic stimulation.

Indications:

Salbutamol is a direct-acting sympathomimetic agent with predominantly beta-adrenergic activity and a selective action on beta receptors (beta₂ agonist) Salbutamol and Salbutamol sulphate are used as bronchodilators in management of disorders involving reversible airways obstruction such as asthma. And in some patients with chronic obstructive pulmonary disease, Salbutamol also decreases uterine contractility and may be given as the sulphate to arrest premature labour.

Dosage and Administration (directions for use):

Children 2-6 years

1-2mg three or four times a day.

Children 6-12 years:

2mg three or four times a day.

Children over 12 years:

2-4mg three or four times a day.

Adults

4mg three to four times a day and can be increased to 8mg three to four times a day

Children under 2 years:

Not recommended.

Precautions & Warnings:

The risk of pulmonary oedema in women being treated with Salbutamol for premature labour means that the patient's state of hydration and heart rate should be monitored carefully. Other risk factors with this form of treatment include multiple pregnancies, a history of cardiac diseases, and maternal infection.

Contraindications: Salbutamol is contraindicated for patients known to have hypersensitivity to the product.

Adverse reactions / Side effects: Salbutamol may cause fine tremor of skeletal muscle (particularly the hands), palpitations, and muscle cramps. Slight tachycardia, tenseness, headaches, and peripheral vasodilation have been reported in large doses.

Storage: Store under normal storage condition (15°C to 30°C). Protect from light.

Keep all medicines out of reach of children.

Packing & Presentation: A bulk pack of 1000's tablets.

Blister pack of 10 x 10 tablets.

MANUFACTURED BY:
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A Milestone To Golden Health