

Aerodyl®

Bambuterol Hydrochloride

Composition:

Aerodyl® 10 mg: Each tablet contains Bambuterol Hydrochloride BP 10 mg.

Aerodyl® 20 mg: Each tablet contains Bambuterol Hydrochloride BP 20 mg.

Aerodyl® Oral solution: Each 5 ml contains Bambuterol Hydrochloride BP 5 mg.

Indications: Bronchial asthma. Chronic bronchitis, emphysema, and other lung diseases, where bronchospasm is a complicating factor. Bambuterol is not intended to treat acute asthma attacks.

Dosage: Bambuterol is a once-daily medication, preferably given shortly before bedtime. The dose is individual. Bambuterol should be used as maintenance therapy, in addition to corticosteroids, in asthma and other pulmonary diseases where bronchospasm is a complicating factor.

Adults and the elderly: In general, the recommended initial dose is 10 mg once-daily, which may be increased to 20 mg once-daily after 1-2 weeks. For those patients who have previously tolerated oral beta₂ agonists well, the recommended initial dose is 20 mg once-daily. For patients with an impaired renal function (GFR < 50 mL/min), the recommended initial dose is 5 mg once-daily, which may be increased to 10 mg once-daily after 1-2 weeks.

Children 2–5 years: 5 mg or 5 ml (1 teaspoonful) once-daily.

Children 6–12 years: 10 mg or 10 ml (2 teaspoonfuls) once-daily.

Contraindications: Hypersensitivity to bambuterol or terbutaline.

Warnings and Precautions: In patients with liver cirrhosis, the direct use of the active metabolite, terbutaline, is preferable. Patients with impaired renal function should receive half the recommended dose. Caution in patients with thyrotoxicosis and severe cardiovascular disorder. Additional blood glucose controls are recommended initially in diabetic patients. The hypokalemic effect of beta₂-agonists may be potentiated by concomitant treatments (see Interactions). Particular caution is recommended in acute severe asthma. Serum potassium levels should be monitored in those situations.

Pregnancy and lactation: As with other drugs administered during pregnancy, the benefits for the mother should be weighed against the risks for the fetus. It is not known whether bambuterol or intermediary metabolites pass into breast milk. Terbutaline does pass into breast milk, but an effect on the infant is unlikely at therapeutic doses.

Side effects: Tremor, headache, tonic muscle cramps, and palpitations have been recorded. Tolerance to these effects usually develops within 1–2 weeks. Urticaria and exanthema may occur. Sleep and behavioral disturbances have been observed.

Drug interactions: Bambuterol prolongs the muscle-relaxing effect of suxamethonium (succinylcholine). This should also be considered for other muscle relaxants which are metabolized by plasma cholinesterase. The effect of beta-agonists may be inhibited by beta-receptor blocking agents (especially those which are non-selective). Concomitant treatment with xanthines, steroids, or diuretics may potentiate hypokalemia.

Commercial pack:

Aerodyl® 10 mg: Box containing 10 X 10 tablets in blister pack.

Aerodyl® 20 mg: Box containing 10 X 10 tablets in blister pack.

Manufactured by:
 **Silva**
Pharmaceuticals Limited
Majdee, Noakhali, Bangladesh