

گولیاں

بیمٹیل®

ہیمیوٹیروپول ہائیڈروکلورائیڈ بی. پی. ۱۰ ملی گرام / ۲۰ ملی گرام

دَمہ کے لیے مؤثر دوا

خوراک:

ابتدائی تجویز کردہ خوراک ۱۰ ملی گرام روزانہ دن میں ایک مرتبہ سونے سے پہلے ہے۔ تاہم بہتر نتائج کی صورت میں ایک یا دو ہفتوں کے بعد ۲۰ ملی گرام دن میں ایک مرتبہ تک بڑھائی جاسکتی ہے۔ گردے کے ایسے مریض جن کا $GFR \leq 50 \text{ ml/min}$ ہو ان کے لیے تجویز کردہ ابتدائی خوراک ۵ ملی گرام ہے۔

ہدایات:

- * دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
- * دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
- * تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

بیمٹیل ۱۰ ملی گرام گولیاں (۱۰x۳) ایلو۔ ایلوپیک میں دستیاب ہیں۔
بیمٹیل ۲۰ ملی گرام گولیاں (۱۰x۳) ایلو۔ ایلوپیک میں دستیاب ہیں۔



Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Bamtel®

Tablets

Bambuterol HCl B.P. 10mg & 20mg

Anti-Asthmatic

COMPOSITION:

Each tablet contains:

Bambuterol hydrochloride B.P.10mg

Bambuterol hydrochloride B.P.20mg

CLINICAL PHARMACOLOGY:

Bambuterol Hydrochloride is a prodrug of the adrenergic beta-receptor agonist terbutaline, which predominantly stimulates beta-2-receptor, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibition of edema caused by endogenous mediators and increased mucociliary clearance.

About 20% of an oral dose of bambuterol is absorbed. The absorption is not influenced by concomitant intake of food. After absorption, bambuterol is slowly metabolized via hydrolysis (plasma cholinesterase) and oxidation to active terbutaline. About 1/3 of the absorbed dose of bambuterol is metabolized in the intestinal wall and in the liver, mainly to intermediary metabolites. Of the administered dose of bambuterol, about 10% is converted to terbutaline.

PHARMACOKINETICS:

Maximum plasma concentration of the active metabolite terbutaline is achieved within 2-6 hours. The effect-duration is at least 24 hours. Steady-state is reached after 4-5 days of treatment. The plasma half-life of bambuterol after oral administration is about 13 hours. The plasma half-life of the active metabolite terbutaline is about 17 hours. Bambuterol and its metabolites, including terbutaline, are mainly excreted via the kidneys.

INDICATIONS:

Bamtel is used for the treatment of bronchial asthma, chronic bronchitis, emphysema and other lung diseases, where bronchospasm is a complicating factor.

DOSAGE & ADMINISTRATION:

Bambuterol hydrochloride is taken once daily, shortly before bedtime. The dose should be individual.

Adults: Recommended initial dose is 10mg. Depending on the clinical effect, the dose may be increased to 20mg after one to two weeks.

In patients with impaired renal function (Glomerular Filtration Rate ≤ 50 ml / min) the recommended initial dose is 5mg.

CONTRA-INDICATIONS:

Bambuterol hydrochloride is contra-indicated for those individuals who are hypersensitive to any component of the product or to terbutaline.

PRECAUTIONS & WARNINGS:

Bambuterol hydrochloride should be used with caution when an increased susceptibility to sympathomimetic amines can be expected, e.g. in patients with hyperthyroidism not yet under adequate control. Since beta-2-agonists may increase the blood glucose level, additional blood glucose controls are recommended when asthmatic patients with concomitant diabetes are started on **Bamtel**. Beta-2-agonists have successfully been used in the acute treatment of severe ischemic heart failure. However, these drugs have an arrhythmogenic potential which must be considered in the treatment of the individual patient. As terbutaline is excreted mainly via the kidneys, the initial dose of Bambuterol hydrochloride should be reduced in patients with severely impaired renal function. An unpredictable interindividual variation in the metabolism of bambuterol hydrochloride to terbutaline has been shown in subjects with liver cirrhosis. Thus, for the same dose of Bambuterol hydrochloride some subjects with liver cirrhosis generated more terbutaline than normal subjects while, in some cases very little or no terbutaline was generated. In patients with liver cirrhosis, and probably in patients with other causes of severely impaired liver function as well, the daily dose must therefore be individualized, taking into account the possibility that the individual patient is unable to metabolize bambuterol to terbutaline. Therefore, from a practical point of view, the direct use of the active metabolite, terbutaline, is preferable in these patients.

DRUG INTERACTIONS:

Bambuterol may prolong the muscle-relaxing effect of suxamethonium (succinylcholine). This is due to the fact that plasma

cholinesterase, which inactivated suxamethonium, is partly inhibited by bambuterol. The inhibition is dose dependent and fully reversible. Beta-receptor blocking agents, especially non-selective ones, may partly or totally inhibit the effect of beta-stimulants.

NURSING MOTHERS:

Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECTS:

Tremor, headache, tonic muscle cramps and palpitation. The intensity of the adverse reactions is dose-dependent. Majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment.

OVERDOSAGE:

Overdosing would result in high levels of terbutaline, sign and symptoms including headache, anxiety, tremor, tonic muscle cramps, palpitation, arrhythmia and hypotension in some cases.

TREATMENT:

Mild and moderate cases: Reduce the dose. Then increase the dose more slowly if the bronchodilating effect is insufficient.

Severe Cases: Gastric lavage, activated charcoal, determine acid-base balance, blood glucose and electrolytes. Monitor heart rate, rhythm and blood pressure. Metabolic changes should be corrected. A cardio-selective beta-blocker (e.g. metoprolol) is recommended for the treatment of arrhythmias causing haemodynamic deterioration. Beta-blockers should be used with care because of the possibility of inducing bronchial obstruction. If the beta-2-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

STORAGE:

- * Store in cool and dry place.
- * Protect from heat, light and moisture.
- * Keep all medicines out of the reach of children.

PACKING:

Bamtel 10mg tablets are available in (3 x 10) Alu-Alu pack.

Bamtel 20mg tablets are available in (3 x 10) Alu-Alu pack.