PULMITEROL

(Bambuterol HCl)

پلمی ٹیرول

(بیمبیوٹیرول ہائیڈروکلورائیڈ)

۱۰ ملی گرام گولیاں

۵ ملی گرام/ ۵ ملی لیٹر اورل سلوشن

Tablets 10 mg
Oral Solution 5 mg / 5ml

COMPOSITION
Each tablet contains:
Bambuterol HCl (B.P.).....10 mg
Product Complies Kaizen Specs.

Each 5ml contains:
Bambuterol HCl (B.P.).....5 mg
Product Complies Kaizen Specs.

DESCRIPTION
PULMITEROL contains bambuterol, a prodrug of the adrenergic beta-receptor agonist terbutaline, which predominantly stimulates beta-2-receptors, 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.
Both bambuterol and the intermediary metabolites in mice, shown to have an affinity for lung tissue, where metabolism to terbutaline also takes place. Thus, an enhanced concentration of the active drug might be achieved in the lung. 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 h. The plasma half-life of the active metabolite terbutaline is about 17 h. Bambuterol and its metabolites, including terbutaline, are mainly excreted via the kidneys.

INDICATIONS
Bronchial asthma, chronic bronchitis, emphysema and other lung diseases, where bronchospasm is a complicating factor.

DOSAGE
PULMITEROL is taken once daily, shortly before bed-time. The dose should be individual.
Children: 2-5 years: The recommended normal dose is 5 mg (5ml).
6-12 years: The recommended initial dose is 5 mg (5ml). The dose may be increased after 1-2 weeks, depending on the clinical effects.
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 (GFR>50ml/min) the recommended initial dose is 5mg.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients or to terbutaline.

ADVERSE REACTIONS
Adverse reactions which have been recorded, e.g. tremor, headache, tonic muscle cramps and palpitation, are all characteristic of sympathomimetic amines. The intensity of the adverse reactions is dose-dependent. Majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment.

PRECAUTIONS
PULMITEROL 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 PULMITEROL.
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 PULMITEROL should be reduced in patients with severely impaired renal function.
An unpredictable interindividual variation in the metabolism of bambuterol to terbutaline has been shown in subjects with liver cirrhosis. Thus, for the same dose of PULMITEROL 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.

USE IN PREGNANCY AND LACTATION
Although no teratogenic effects have been observed in animals after administration of bambuterol, caution is recommended during the first trimester of pregnancy. It is not known whether bambuterol or intermediary metabolites pass over to breast milk. Terbutaline passes over to breast milk but an influence on the child is unlikely with therapeutic doses. Transient hypoglycemia has been reported in newborn preterm infants after maternal beta-2-agonist treatment.

DRUG INTERACTIONS
Bambuterol may prolong the muscle-relaxing effect of suxamethonium (succinylcholine). This is due to the fact that plasma cholinesterase, which inactivates suxamethonium, is partly inhibitied 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.

OVERDOSAGE
No case of Bambuterol overdosage has yet been reported. However, it is likely that overdosing would result in high levels of terbutaline and therefore the same symptoms and signs as recorded after overdosage of Terbutaline: Headache, anxiety, tremor, tonic muscle cramps, palpitation and arrhythmia. A fall in blood pressure sometimes occurs after terbutaline overdosage.
Laboratory findings: hyperglycemia and lactacidosis sometimes occur. High doses of beta-2-agonists may cause hypokalemia as a result of redistribution of potassium, but this does not usually require treatment.
Overdosage of PULMITEROL is also likely to cause a considerable inhibition of plasma cholinesterase, that may last for days (see also under “Drug interactions”).

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 a haemodynamic deterioration. Beta-blockers should be used with care because of the possibility of inducing bronchial obstruction. A volume expander should be given if the beta-2 mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
PULMITEROL does not affect the abillity to drive or use machines.

INCOMPATIBILITIES
Not applicable to this dosage form.

PRESENTATION:
PULMITEROL 10 mg tablet available in blister pack of 30’s.
PULMITEROL 5mg/5ml oral solution availalbe in 60 ml pack size.

DOSAGE: As directed by physician.
To be dispensed on the prescription of a registered medicalpractitioner only. Store below 30ºC in a dry place, protect from light. Keep out of the reach of children. Keep bottle tightly closed.

- **خوراک:** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔ • ڈھکن کو اچھی طرح بند رکھیں۔

Manufactured by:
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