BTno™

(Bambuterol HCl)

10mg 20mg Tablets

5mg/5ml Syrup

بی ٹی نو

(بیمبیوٹیرول ہائیڈروکلورائیڈ)

۱۰ ملی گرام، ۲۰ ملی گرام ٹیبلٹس

۵ ملی گرام/۵ ملی لیٹر سیرپ

DESCRIPTION:

BTno contains Bambuterol HCl which is potent bronchodilator. Bambuterol is a prodrug of the adrenergic beta- receptor agonist, terbutaline.

COMPOSITION:

BTno 10mg Tablets:

Each tablet contains: Bambuterol HCl B.P. 10mg

Innovator's Specifications

BTno 20mg Tablets:

Each tablet contains: Bambuterol HCl B.P. 20mg

Genix Specifications

Btno Syrup:

Each 5mL contains: Bambuterol HCl B.P. 5mg

Genix Specifications

MODE OF ACTION

BTno predominantly stimulates ß2-receptors, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibition of oedema caused by endogenous mediators and increased mucociliary clearance.

PHARMACOKINETICS

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 metabolised 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 in adults. Children have a reduced clearance of terbutaline, but they also generate less terbutaline than adults. Therefore children aged 6-12 years should be given adult doses, whereas smaller children (2-5 years) usually need less. Due to differences in kinetics, Oriental children should receive a low dose of bambuterol. The kinetics in elderly patients differs little from younger adults. Maximum plasma concentration of the active metabolite terbutaline is achieved within 2 to 6 hours. The effect duration is at least 24 hours. Steady-state is achieved after 4 to 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 21 hours. The protein binding of bambuterol is low. At therapeutic concentrations, overall plasma protein binding is approximately 40 to 50%. Bambuterol and its metabolites, including terbu-

taline, are mainly excreted via the kidneys. Patients with renal failure (GFR • 50 ml/min) and patients with severely impaired hepatic functions may display altered pharmacokinetics which would necessitate dose individualization.

INDICATIONS

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

DOSAGE AND ADMINISTRATION

BTno is dosed once daily, preferably shortly before bedtime. The dose should be individualized.

TABLETS: ADULTS: The recommended initial dose is 10 mg. The dose may be increased to 20 mg after one to two weeks depending on the clinical effect. Doses higher than 20 mg do not provide a significant increase in effect and can cause increase in common adverse events. In patients who previously have tolerated oral ß2-agonists well, the recommended initial dose is 20mg.

SYRUP: CHILDREN: 2-5 years: The recommended normal dose is 1 teaspoon. **6-12 years:**The recommended initial dose is 1 teaspoon. The dose may be increased after 1-2 weeks, depending on the clinical effects. **ADULTS:** Recommended initial dose is 2 teaspoons, depending on the clinical effects, the dose may be increased to 4 teaspoons after one to two weeks.

CONTRAINDICATIONS

Contraindicated in pregnancy Hypersensitive and seriously impaired liver functions.

ADVERSE EFFECTS

Adverse reactions which have been recorded are all characteristic of sympathomimetic amines. The intensity of the adverse reactions is dose-dependent. Tolerance to these effects has usually developed within one to two weeks. **Common (1%)** Headache Palpitations, tremor, tonic muscles, cramps, urticaria and exanthema Rare (< 0.1%) Hypokalaemia, Nausea, restlessness, atrial fibrillation, supraventricular tachycardia and extrasystoles.

PRECAUTIONS

As for all ß2-agonists caution should be observed in patients with thyrotoxicosis and in patients with severe cardiovascular disorder, such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Due to the hyperglycemic effects of ß2-agonists, additional blood glucose controls are recommended initially in diabetic patients. Potentially serious hypokalaemia may result from ß2-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalaemic effect may be potentiated by concomitant treatments (see INTERACTIONS). It is recommended that serum potassium levels are monitored in such situations. As terbutaline is excreted mainly via the kidneys, the initial dose of BTno should be halved in patients with an impaired renal function (GFR • 50 ml/min). In patients with liver cirrhosis, and probably in patients with other causes of severely impaired liver function, the daily dose must be individualized.

PREGNANCY AND LACTATION

It is not known whether bambuterol or intermediary metabolites pass over

to breast milk, so caution is recommended if bambuterol is administered to patients who are breastfeeding. Terbutaline passes over to breast milk but an influence on the child is unlikely with therapeutic doses. Transient hypoglycaemia has been reported in newborn pre-term infants after maternal ß2-agonist treatment.

INTERACTIONS
Suxamethonium (succinylcholine) and other muscle relaxants, beta-stimulants, xanthine derivatives and diuretics.

OVERDOSAGE
No case of BTno overdosage has yet been reported in humans. 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 like headache, anxiety, tremor, nausea, tonic muscle cramps, palpitations, tachycardia, cardiac arrhythmias, low blood pressure.

TREATMENT OF OVERDOSAGE
Usually no treatment is required. In severe cases of overdosage, some measures should be considered like gastric lavage & activated charcoal. Determine acid-base balance, blood glucose and electrolytes. Monitor heart rate and rhythm and blood pressure. The preferred antidote for overdosage with BTno is a cardioselective beta-blocking agent, but beta-blocking agents should be used with caution in patients with a history of bronchospasm. If the ß2-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

INSTRUCTIONS:
Dosage as directed by the physician.
Tablets: Store below 30°C. Protect from heat, light & moisture.
For Oral use Only.
Syrup: Store below 30°C. Protect from heat & light.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only

PRESENTATION
BTno 10mg tablets are available in Alu-PVC blister pack of 2 x 15's.
BTno 20mg tablets are available Alu-PVC blister pack of 2 x 15's.
BTno syrup is available in 120mL Pet bottle.

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

ٹیبلٹس: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔

گرمی، روشنی اور نمی سے محفوظ رکھیں۔

سیرپ: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔

گرمی اور روشنی سے محفوظ رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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