Breavent™ 200

(Salbutamol)

Highnoon

COMPOSITION
Breavent 200 Rotacaps: Each capsule contains:
Salbutamol (as Sulphate) 200mcg

DESCRIPTION
Salbutamol is a short-acting β_2-adrenergic receptor agonist and the tertiary butyl group in salbutamol (or albuterol) makes it more selective for β_2-receptors.
Salbutamol is beta$_2$ adrenergic stimulant which has a highly selective action on the receptors in bronchial muscle resulting in bronchodilatation.

MECHANISM OF ACTION
Salbutamol produces bronchodilation through stimulation of beta$_2$-adrenergic receptors in bronchial smooth muscle, thereby causing relaxation of bronchial muscle fibres. Beta$_2$-receptors are the predominant adrenergic receptors in bronchial smooth muscle and beta$_1$-receptors are the predominant receptors in the heart. The precise function of these receptors has not been established, but they raise the possibility that even highly selective beta$_2$-agonists may have cardiac effects. At therapeutic doses, salbutamol has little action on the beta$_1$-adrenergic receptors in cardiac muscle.

PHARMACOKINETIC
Salbutamol is readily absorbed from the gastrointestinal tract. When given by inhalation, 10 to 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is swallowed and absorbed from the gut. Salbutamol is subject to first-pass metabolism in the liver and possibly in the gut wall, but does not appear to be metabolized in the lung; the main metabolite is an inactive sulphate congjugate. Salbutamol is rapidly excreted mainly in the urine, as metabolites and unchanged drug; there is some excretion in the faeces. The plasma half-life of the Salbutamol has been estimated to ranges from 4 to 6 hours.

INDICATION
- It is indicated for the symptomatic relief and prevention of bronchospasm due to bronchial asthma, chronic bronchitis and other chronic bronchopulmonary disorders in which bronchospasm is a complicating factor.
- It is used for the prevention of exercise-induced bronchospasm.
- It can be used in the management of reversible airways obstruction.
- It can also be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack e.g. unavoidable allergen exposure.

DOSAGE AND ADMINISTRATION
Breavent Rotacaps are for inhalation use only through Rotaflo or Revolizer.
For relief of acute episodes of bronchospasm:

Adults
One or two capsules as single dose. The maximum daily dose is four capsules or 800mcg in a day.

Children
Children aged 4 to 11 years: one capsule (200mcg) as required.
Children aged 12 years and over: Dose as per adult population

To prevent allergen or exercise induced bronchospasm:

Adults
1 capsule (200mcg) should be taken 15 minutes before exercise

Children
Children aged 4 to 11 years: 1 capsule (200mcg) before challenge or exertion.
Children aged 12 years and over: Dose as per adult population.

Chronic therapy
Children aged 4 to 11 years: 1 capsule (200mcg) four times a day.
Children aged 12 years and over: Dose as per adult population

CONTRAINDICATIONS
Hypersensitivity to any of the components of the formulation.

ADVERSE EVENTS
The reported adverse events are; nervousness, fine tremor of the skeletal muscle (particularly hands), peripheral vasodilatation, paradoxical bronchospasm, hypokalaemia, hyperglycaemia, cardiac arrhythmias (including supraventricular tachycardia, atrial fibrillation, extrasystoles), drowsiness, flushing, restlessness, irritability, chest discomfort, difficulty in micturition, hypertension, angina, vomiting, vertigo, central nervous system stimulation, hyperactivity in children, unusual taste and drying or irritation of the oropharynx, headache, palpitations, transient muscle cramps, insomnia, nausea, weakness, dizziness, immediate hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension, rash, oropharyngeal oedema, anaphylaxis, collapse, hyperactivity in children, sleep disturbances, hallucination or atypical psychosis has been reported.

DRUG INTERACTIONS
- Use of Salbutamol and other Beta2-agonists with corticosteroids, diuretics, or xanthines increases the risk of hypokalaemia, and monitoring of potassium concentrations is recommended in severe asthma where such combination therapy is common. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.
- Beta-adrenergic-receptor blocking agents not only block the pulmonary effect of beta-agonists but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, eg, as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-adrenergic-blocking agents in patients with asthma. In this setting, consider cardioselective beta-blockers, although they should be administered with caution.
- Administer with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salbutamol on the cardiovascular system may be potentiated. Consider alternative therapy in patients taking MAO inhibitors or tricyclic antidepressants.

WARNING AND PRECAUTIONS
- Care should be taken with patients suffering from cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias and hypertension. Special care and supervision are required in patients with idiopathic hypertrophic subvalvular aortic stenosis, in whom an increase in the pressure gradient between the left ventricle and the aorta may occur, causing increased strain on the left ventricle.
- In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression.
- Fatalities have been reported in association with excessive use of inhaled Sympathomimetic drugs in patients with asthma. The exact cause of death is unknown, but cardiac arrest following an unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected.
- Beta-adrenergic agents, salbutamol sulphate can induce reversible metabolic changes such as potentially serious hypokalemia. Particular caution is advised in acute severe asthma since hypokalemia may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics and by hypoxia. Hypokalemia will increase the susceptibility of digitalis-treated patients to cardiac arrhythmias. It is recommended that serum potassium levels be monitored in such situations.
- Care should be taken with patients with diabetes mellitus, hyperthyroidism and convulsive disorder.
- Immediate hypersensitivity reactions may occur after administration of salbutamol. Care should be taken in patients who are unusually responsive to sympathomimetic amines, as with other inhaled medications, paradoxical bronchospasm may occur characterized by an immediate increase in wheezing after dosing.
- Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses of Salbutamol, this may be a marker of destabilization of asthma and requires re-evaluation of the patient and treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, eg, corticosteroids.
- The use of beta-adrenergic-agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids, to the therapeutic regimen.
- The safety and effectiveness of the drug in asthma patients 4 to <12 years of age has not been established. The potential growth effects of prolong treatment should be weighed against the clinical benefits obtained before prescribing the drug in children 4 < 12 years of age. The safety and effectiveness of the drug in asthma patients <4 years of age has not been established.

USED IN SPECIAL POPULATION
Pregnancy
There are no adequate and well-controlled studies in pregnant women and there is little published evidence of its safety in the early stages of human pregnancy. Administration of any drug to pregnant women should only be considered if the anticipated benefits to the expectant woman are greater than any possible risks to the fetus.
Various studies shown that, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with salbutamol.

Labour or Delivery
Because of the potential for beta-agonist interference with uterine contractility, use of Salbutamol for relief of bronchospasm during labour should be restricted to those patients in whom the benefits clearly outweigh the risk, Serious adverse reactions, including pulmonary edema, have been reported during or following treatment of premature labour with beta2-agonists, including albuterol.

Nursing Women
Plasma level of Salbutamol after inhaled therapeutic doses are very low in humans, but it is not known whether the components are excreted in human milk. The possibility of fetal harm is remote if the corticosteroids are distributed into milk. Because of the potential for serious adverse reactions from Salbutamol in nursing infants, a decision should be made whether to discontinue nursing or Salbutamol, taking into account the importance of the drug to the woman.

OVERDOSAGE
The expected symptoms of the over dosage are those of excessive beta adrenergic stimulation or exaggeration of any of the symptoms listed under adverse effects, seizures, angina, tachycardia, tremors, hyperglycaemia, cardiac arrhythmia, hypokalaemia, hypertension, hypotension, nervousness and fatigue, dry mouth, palpitation, nausea, dizziness, malaise, and insomnia.
As with all the sympathomimetic medications, cardiac arrest and even death may be associated with abuse of Salbutamol.

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in dry place. Protect from light.

ROTACAPS ARE INTENDED FOR USE THROUGH ROTAFLO OR REVOLIZER ONLY AND ARE NOT TO BE SWALLOWED.

PRESENTATION
Breavent Rotacaps 200mcg: Bottle of 30 Rotacaps.

بریوینٹ™ ۲۰۰

(سالبیوٹامول)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

روٹاکیپسولز کھانے کے لئے نہیں۔

صرف روٹافلو یا ریوولائزر کے ذریعے استعمال کریں۔

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