VENTISAL COZYCAP

Salbutamol 200 mcg BP

Compositions:
Each inhalation capsule contains Salbutamol Sulfate BP equivalent to Salbutamol 200 microgram.

Pharmacology:
Salbutamol is a synthetic sympathomimetic agent with predominant beta-2 adrenergic activity. Salbutamol produces bronchodilatation through stimulation of beta-2-adrenergic receptors in bronchial smooth muscles, thereby causing relaxation of bronchial muscle fibers.

Dosage And Administration:
Adults: For the relief of bronchospasm and for managing intermittent episodes of asthma, one or two inhalation capsule may be administered as a single dose. The usual recommended dosage of Salbutamol inhalation capsule for inhalation for adults for maintenance or prophylactic therapy is the contents of one 200 microgram capsule every 4 to 6 hours using a CapHaler device. In some patients, the contents of two 200 microgram capsules inhaled every 4 to 6 hours may be required. Large doses or more frequent administration is not recommended. The use of salbutamol powder for inhalation can be continued as medically indicated to control recurring/intermittent episodes of bronchospasm. Children: One Salbutamol inhalation capsule is the recommended dose for relief of acute bronchospasm in the maintenance of episodic asthma or before exercise of children 4 years of age and older. One inhalation should be administered for three or four times a day for routine maintenance or prophylactic therapy. This dosage may be increased to inhalation of two inhalation capsule, if necessary. The bronchodilator effect of each administration of inhaled Salbutamol inhalation capsule lasts for at least four hours. Such patients should be warned not to increase the dose of inhaler, but should seek medical advice immediately. Exercise-induced Asthma: Adults: 400 microgram, Child: 200 microgram,15-30 minutes prior to any physical exertion.

Contraindications:
If additional adrenergic drugs are administered to patients using Salbutamol cozycap they should be used with caution to avoid deleterious cardiovascular effects. Concomitant administration of salbutamol and non-selective ß -blocking drugs such as Propranolol is not recommended. Patients treated with monoamine oxidase inhibitors or tricyclic antidepressants should be followed clinically in the beginning of salbutamol treatment, because the action of salbutamol on the vascular system may be potentiated. The simultaneous administration of xanthines, corticosteroids or potassium excreting diuretics may increase hypokalaemia.

Warning And Precaution:
In the event of a previously effective dose of Salbutamol inhaler, failing to give relief for at least three hours, the patients should be advised to seek medical advice. Salbutamol and other β2 agonists should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT interval prolongation, hypertension, and diabetes mellitus. Pharmaceutical precautions: Cozycap must not be swallowed. Don’t exceed the recommended dose. Keep away from light and moisture, store in a cool and dry place. Rinsing out mouth with water immediately after inhalation. Insert the cozycap in the CapHaler just prior use, as Cozycap exposed to moisture may not tear easily.

Side Effects:
Salbutamol may cause fine tremor of skeletal muscle (particularly of the hands), palpitations, and muscle cramps. Tachycardia, headache, and peripheral vasodilatation have been reported

after large dose. They usually disappear with continued treatment. Hypersensitive reactions including angioedema and urticaria, bronchospasm, hypotension and collapse have been reported very rarely. As with all inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy should be instituted.

Use in Pregnancy and Lactation:
Inhalation has particular advantage as a mean of administration of β2 agonist during pregnancy as the therapeutic action can be achieved without the requirement for such plasma concentration liable to have a pharmacological effect on the fetus. Although there is no evidence that salbutamol is teratogenic, it should be used in the first trimester only if absolutely essential. Salbutamol probably enters breast milk, but the concentration is unknown. However, no adverse effects have been reported in the breast-fed babies of mothers taking the drug by inhalation.

Drug Interaction:
If additional adrenergic drugs are administered to patients using Salbutamol cozycap they should be used with caution to avoid deleterious cardiovascular effects. Concomitant administration of salbutamol and non-selective ß -blocking drugs such as Propranolol is not recommended. Patients treated with monoamine oxidase inhibitors or tricyclic antidepressants should be followed clinically in the beginning of salbutamol treatment, because the action of salbutamol on the vascular system may be potentiated. The simultaneous administration of xanthines, corticosteroids or potassium excreting diuretics may increase hypokalaemia.

Overdosage:
The symptoms with overdosage are angina, headache, nausea, vomiting, tremor etc. The preferred antidote for overdosage with Salbutamol is acardio-selective beta-blocking agent but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

Storage:
Store in cool and dry place (below 30ºC), protect from light. Keep out of reach of children.

Packing:
Each box contains 3x10 Cozycaps in Alu-Alu blister pack for use with CapHaler Device.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.