Albutamol® Neo

1. Composition

Salbutamol 1mg

Etofylline 50mg

2. Dosage form and strength

Albutamol neo Syrup is available in 100 ml bottle.

3. Clinical particulars

3.1 Therapeutic indication

Albutamol neo Syrup is indicated for the treatment of productive cough associated with bronchospasm in conditions such as bronchitis and bronchial asthma as well as all conditions associated with tenacious mucus, wheezing and chest congestion.

3.2 Posology and method of administration

The usual recommended oral dose of Albutamol neo Syrup for children is 5-10ml thrice a day.

3.3 Contraindication

Albutamol neo Syrup is contraindicated in patients with hypersensitivity to any ingredient of the formulation.

3.4 Special warnings and precautions for use

- While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause, such as a specific infection.
- Caution should be observed while prescribing Albutamol Plus Syrup to children with hypertension, cardiovascular disease, uncontrolled juvenile diabetes mellitus, hyperthyroidism, seizures or in patients who are unusually hypersensitive to sympathomimetic amines.

3.5 Drug interactions

- Hypokalemia with high doses of ß2 -agonists may result in increased susceptibility to digitalis induced cardiac arrhythmias.
- Hypokalemia may be enhanced by concomitant administration of aminophylline or other xanthines, corticosteroids or by diuretic therapy.
- Other sympathomimetic bronchodilators or epinephrine should not be used concomitantly with salbutamol, since their combined effect on the cardiovascular system may be deleterious to the patient.
- Salbutamol should be administered with caution in patients being treated with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants, since the action of salbutamol on the vascular system may be potentiated.

3.6 Use in special population

- Pediatric: Safe.
- Geriatric: Safety and effectiveness of Albutamol neo Syrup in geriatric patients have not been established.
- Liver impairment: Use with caution.
- Renal failure: Use with caution.
- Pregnancy and lactation: Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. Doctor consultation is recommended for breast feeding patients.

3.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Albutamol neo Syrup is known.

3.8 Undesirable effects

- The adverse reactions to Salbutamol are similar in nature to those of other sympathomimetic agents and include nervousness and tremor.
- The frequency of these side effects appears to diminish with continued therapy.
- Other commonly reported reactions include increased heart rate, palpitations, dizziness, headache, drowsiness, vomiting, nausea, sweating and muscle cramps. These reactions are generally transient and usually do not require treatment.

3.9 Overdose

There is limited experience of overdose with Albutamol neo Syrup. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

Salbutamol is a beta (2)-adrenergic agonist and thus it stimulates beta (2)-adrenergic receptors. Binding of albuterol to beta (2)-receptors in the lungs results in relaxation of bronchial smooth muscles. It is believed that salbutamol increases cAMP production by activating adenylate cyclase, and the actions of salbutamol are mediated by cAMP. Increased intracellular cyclic AMP increases the activity of cAMP-dependent protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular calcium concentrations. A lowered intracellular calcium concentration leads to a smooth muscle relaxation and bronchodilation. In addition to bronchodilation, salbutamol inhibits the release of Broncho constricting agents from mast cells, inhibits microvascular leakage, and enhances mucocilliary clearance.

Etofylline is the ethyl salt of Theophylline. It inhibit phosphodiesterase enzyme which degrades cyclic nucleotides intracellularly and it results the cyclic AMP accumulation in the cell. This cause bronchodilation

4.2 Pharmacodynamic properties

Salbutamol, a moderately selective beta (2)-receptor agonist similar in structure to terbutaline, is widely used as a bronchodilator to manage asthma and other chronic obstructive airway diseases. The R-isomer, levalbuterol, is responsible for bronchodilation while the S-isomer increases bronchial reactivity. The R-enantiomer is sold in its pure form as Levalbuterol. The manufacturer of levalbuterol, Sepracor, has implied (although not directly claimed) that the presence of only the R-enantiomer produces fewer side-effects.

Etofylline release calcium from sarcoplasmic reticulum, especially in cardiac muscles and results increased cardiac muscle contraction. This drug also blocks adenosine receptors (adenosine acts as a local mediator in CNS & CVS and other organs- which contracts smooth muscles, especially in bronchi, blood vessels etc). This results in bronchodilation and vasodilatation.

4.3 Pharmacokinetic properties

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 metabolised

in the lung; the main metabolite is the inactive sulfate conjugate. Salbutamol is rapidly excreted, mainly in the urine, as metabolites and unchanged drug; a smaller proportion is excreted in the faeces. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

Etofylline is well absorbed after oral administration. Rapidly and well absorbed after intravenous administration. Widely distributed in the body and 40% bound to the plasma proteins.
Metabolized in the liver to its metabolites by demethylation and oxidation. 1-methyluric acid is its metabolite excreted through urine.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

24 months.

7.3 Storage and handling instructions

Store below 30^{o}C in a dark place. Keep the bottle tightly closed.