For the use of Registered Medical Practitioner
or a Hospital or a Laboratory only

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Levosalbutamol Sulphate and Ipratropium Bromide Powder for Inhalation

Qualitative and Quantitative Composition
Each capsule contains:

Levosalbutamol Sulphate IP	
Eq. to Levosalbutamol	100 mcg
Ipratropium Bromide IP	40 mcg
Excipients	q.s.

Colour: Approved colours used in empty capsule shell

Pharmaceutical form
Dry powder for Inhalation

CLINICAL PARTICULARS
Therapeutic indications
It is used to relieve symptoms of COPD (Chronic Obstructive Pulmonary Disease) like breathing difficulties, coughing and whistling sound while breathing and tightness in the chest.

Posology and method of administration
This medicinal product is for inhalation use only. It is used in adults and children over 12 years to treat long term breathing problems (e.g. chronic bronchitis and emphysema). It alleviates wheezing when breathing, shortness of breath and tightness in the chest.

Contraindications
- If you are allergic to atropine or its derivatives
- If you are allergic to Ipratropium or Levosalbutamol or any other ingredients.

Interaction with other medicinal products and other forms of interaction
- Concomitant use of Levosalbutamol Sulphate and Ipratropium Bromide powder for inhalation along with medicines used to treat psychiatric illness (Amitriptyline, selegiline, etc.) or medicines used to treat asthma (Albuterol, Epinephrine) should be avoided as it may alter the effects of this medicine.
- Concomitant use of this medicine with beta-blockers like Propranolol, Labetalol, etc. (used to treat high blood pressure and heart problems), may decrease the effectiveness of Levosalbutamol Sulphate and Ipratropium Bromide powder for inhalation
- Concomitant use of this medicine with water pills like Furosemide, Hydrochlorothiazide may decrease the potassium level in the body which leads to heart rhythm abnormalities. Your doctor may advise the monitoring of blood potassium levels.

Overdose
Levosalbutamol
Symptoms
The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia.

Ipratropium Bromide
No symptoms specific to over dosage have been encountered.

Pharmacological properties
Levosalbutamol
Pharmacodynamic properties
Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists ATC Code: R03CC02 As a beta-adrenergic stimulant for relief of bronchospasm such as occurs with asthma, bronchitis, emphysema. It has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

Pharmacokinetic properties
Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. After multiple oral doses of salbutamol 4mg four times a day, steady-state plasma concentrations are obtained after 3 days. About half is excreted in the urine as an inactive sulphate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%.

Ipratropium bromide
Pharmacotherapeutic group: Anticholinergics, ATC code: R03BB01Ipratropium bromide is a quaternary ammonium compound with anticholinergic (parasympatholytic) properties. In nonclinical studies, it appears to inhibit vagally mediated reflexes by antagonising the action of acetylcholine, the transmitter agent released from the vagus nerve.
Anticholinergics prevent the increase in intracellular concentration of Ca++ which is caused by interaction of acetylcholine with the muscarinic receptor on bronchial smooth muscle. Ca++ release is mediated by the second messenger system consisting of IP3 (inositol triphosphate) and DAG (diacylglycerol).

Pharmacokinetic properties
Absorption
The therapeutic effect of ipratropium bromide is produced by a local action in the airways. Time courses of bronchodilation and systemic pharmacokinetics do not run in parallel.Following inhalation, 10 to 30% of a dose is generally deposited in the lungs, depending on the formulation, device and inhalation technique. The major part of the dose is swallowed and passes through the gastro-intestinal tract.The portion of the dose deposited in the lungs reaches the circulation rapidly (within minutes).

Distribution
The drug is minimally (less than 20%) bound to plasma proteins. Nonclinical data indicate that the quaternary amine ipratropium does not cross the placental or the blood-brain barrier.

Biotransformation
After intravenous administration approximately 60% of the dose is metabolised, mainly by conjugation (40%), whereas after inhalation about 77% of the systemically available dose is metabolised by ester hydrolysis (41%) and conjugation (36%).

Elimination
Ipratropium has a mean total clearance of 2.3 L/min and a renal clearance of 0.9 L/min.

STORAGE:
Store at a temperature not exceeding 25°C, protected from light and moisture.

Keep out of reach of children.

Presentation: It is available in a pack of 30 capsules.

Manufactured by:
Biodeal Pharmaceuticals Limited
(A WHO-GMP CERTIFIED COMPANY)
Vill. Saini Majra, Nalagarh-Ropar Road,
Nalagarh-174101, Distt. Solan (H.P.), India

LLT1412

200.00 mm

130.00 mm

130.00 mm