Iprasol®

Inhaler

Description

Iprasol metered dose inhaler is a combination of Salbutamol BP and Ipratropium Bromide BP. Salbutamol is a short acting β_2 agonist bronchodilator and Ipratropium Bromide is an anticholinergic bronchodilator. When used in combination, they produce greater bronchodilator effect than either agent alone. Iprasol is expected to maximise the response to treatment in patients with chronic obstructive pulmonary disease (COPD) by reducing bronchospasm through two distinctly different mechanisms, anticholinergic (parasympatholytic) and sympathomimetic. Simultaneous administration of both an anticholinergic (Ipratropium Bromide) and a β_2 sympathomimetic (Salbutamol Sulphate) is designed to benefit the patient by producing a greater bronchodilator effect than when either drug is utilised alone at its recommended dosage.

Indications

Iprasol inhalation aerosol is indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.

Dosage and Administration

The dosage of Iprasol should be adapted to the individual requirements of the patient.

Adults (including the elderly and adolescents over 12 years of age): 2 puffs four times a day. Patients may take additional puffs as required; however, the total number of puffs should not exceed 12 puffs in 24 hours.

Children : Not recommended.

Contraindications

Iprasol inhalation aerosol is contraindicated in patients hypersensitive to any components of the product or to atropine or its derivatives. It is also contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soyabean and peanut.

Precautions

General : Iprasol inhalation aerosol contains Ipratropium Bromide and, therefore, it should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction.

Effects seen with sympathomimetic drugs : Preparations containing sympathomimetic amines such as Salbutamol Sulphate should be used with caution in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines. β adrenergic agents may also produce significant hypokalaemia in some patients (possibly through intracellular shunting) which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.

Use in hepatic or renal disease : Iprasol inhalation aerosol has not been studied in patients with hepatic or renal insufficiency. It should be used with caution in these patients.

Paradoxical bronchospasm : Iprasol inhalation aerosol can produce paradoxical bronchospasm that can be life threatening. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted. It should be recognised that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.

Cardiovascular effect : The Salbutamol Sulphate contained in Iprasol inhalation aerosol, like other β adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure and/or other symptoms. Although such effects are uncommon after administration of Iprasol inhalation aerosol at recommended doses, if they occur, discontinuation of the drug may be indicated. In addition, β adrenergic agents have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. Therefore, Iprasol inhalation aerosol should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmia and hypertension.

Immediate hypersensitivity reactions : Immediate hypersensitivity reactions may occur after administration of Ipratropium Bromide or Salbutamol Sulphate, as demonstrated by rare cases of urticaria, angio-oedema, rash, bronchospasm, anaphylaxis and oropharyngeal oedema.

Drug Interactions

Iprasol inhalation aerosol has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines and steroids, commonly used in the treatment of COPD, without adverse drug reactions. No formal drug interaction studies have been performed with Iprasol inhalation aerosol and these drugs or other medications commonly used in the treatment of COPD.

Anticholinergic agents : Although Ipratropium bromide is minimally absorbed into the systemic circulation, there is some potential for an additive interaction with concomitantly used anticholinergic medications. Caution is therefore advised in the co-administration of Iprasol inhalation aerosol with other anticholinergic drugs.

β *adrenergic agents :* Caution is advised in the co-administration Iprasol inhalation aerosol and other sympathomimetic agents due to the increased risk of adverse cardiovascular effects. β receptor blocking agents and Salbutamol inhibit the effect of each other. β receptor blocking agents should be used with caution in patients with hyperreactive airways.

Diuretics : The ECG changes and/or hypokalaemia which may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by β agonists, especially when the recommended dose of the β agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the co-administration of β agonist containing drugs, such as Iprasol inhalation aerosol, with non-potassium sparing diuretics. Iprasol inhalation aerosol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants or within two weeks of discontinuation of such agents because the action of Salbutamol on the cardiovascular system may be potentiated.

Side Effects

Salbutamol : Mild tremor and headache have been rarely reported. These usually disappear with continuous treatment. There have been very rare reports of transient muscle cramp. Hypersensitivity reactions including angio-oedema, urticaria, bronchospasm, hypotension and collapse have been reported very rarely.

Ipratropium : Headache, pain, influenza, chest pain, nausea, bronchitis, dyspnea, coughing, pneumonia, and bronchospasm in lower part, and pharyngitis, sinusitis and rhinitis in the upper part have been reported.

Use in Special Populations

Pregnancy : Pregnancy Category B. Animal studies have demonstrated no evidence of teratogenic effects as a result of Ipratropium bromide. Pregnancy Category C. Salbutamol has been shown to be teratogenic in mice. There are, however, no adequate and well controlled studies of this inhalation aerosol of Ipratropium bromide or Salbutamol Sulphate in pregnant women. Because animal reproduction studies are not always predictive of human response, Iprasol inhalation aerosol should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation : It is not known whether the components of Iprasol inhalation aerosol are excreted in human milk. Because of the potential for tumorigenicity shown for Salbutamol in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Commercial Pack

Iprasol® Inhaler : Each canister of Iprasol contains 200 metered doses for inhalation aerosol with each actuation (Puff) containing 100 μg of Salbutamol BP and 20 μg of Ipratropium Bromide BP.