Seroxyn ®

Inhalation Aerosol
Salmeterol Xinafoate and Fluticasone Propionate

Description

Seroxyn ® inhalation aerosol is a combination of Salmeterol Xinafoate and Fluticasone Propionate. Salmeterol Xinafoate is a selective, long acting beta-2 agonist; it attaches to beta-2 receptors on the smooth muscle cells that surround the airways, causing the muscle cells to relax and opening the airways. Fluticasone Propionate is a synthetic corticosteroid which is a glucocorticoid receptor agonist with mainly potent anti-inflammatory activity. Fluticasone Propionate is stated to exert a topical effect on the lungs without systemic effects at usual dose.

Indications

Seroxyn ® inhaler is indicated in the regular treatment of asthma where use of a combination (long acting beta-2 agonist and inhaled corticosteroid) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta-2 agonist or,
- Patients already adequately controlled on both inhaled corticosteroids and long acting beta-2 agonist.

Dosage and Administration

Adults and adolescents aged 12 years and older:

- **Seroxyn ®** 25/125 Inhaler- 2 inhalations (puffs) twice a day. or,
- **Seroxyn ®** 25/250 Inhaler- 2 inhalations (puffs) twice a day.

Side Effects

As the combination inhaler contains Salmeterol and Fluticasone Propionate, the type and severity of adverse reactions associated with each of the compounds may be expected. There is no incidence of additional adverse events following concurrent administration of the two compounds.

Adverse events, which have been associated with Salmeterol or Fluticasone Propionate, are given below:

Salmeterol: The pharmacological side effects of beta-2 agonist treatment, such as tremor, subjective palpitations and headache have been reported but tend to be transient and reduce with regular therapy. Cardiac arrhythmia (including atrial fibrillation, supraventricular tachycardia and extra systoles) may occur, usually in susceptible patients. There have been reports of arthralgia and hypersensitivity reactions including rash, oedema and angio-oedema. There have been also reports of oropharyngeal irritation. There have been rare reports of muscle cramps.

Fluticasone Propionate: Hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients. Cutaneous hypersensitivity reactions have been reported. Rare cases of facial and oropharyngeal oedema have been reported. Both hoarseness and incidence of candidiasis may be relieved by gargling with water after use of Salmeterol/ Fluticasone Propionate Inhaler. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with this combination inhaler.

Precautions

Consideration should be given to additional corticosteroid therapies and to including administration of antibiotics if an infection is present. As with all inhaled medication containing corticosteroids, this combination inhaler should be administered with caution in patients with active or quiescent pulmonary tuberculosis. This combination inhaler should be administered with caution in patients with thyrotoxicosis.

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered to paediatric patients. The long term effects of this reduction including the impact of final adult height are unknown.

Pregnancy and lactation

There is insufficient experience of the use of Salmeterol Xinafoate & Fluticasone Propionate in human pregnancy & lactation.

Administration of drugs during pregnancy and lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child.

Contraindications

This combination inhaler is contraindicated in patients with a history of hypersensitivity to any of the ingredients.

Drug Interactions

Care should be taken when co administering known strong CYP3A4 inhibitors (e.g., Ketoconazole, Ritonavir), as there is potential for increased systemic exposure to Fluticasone Propionate.

Both non-selective and selective beta-2 blockers should be avoided in patients with asthma, unless there are compelling reasons for their use. Due to the very low plasma concentrations achieved after inhaled dosing clinically significant drug interactions are unlikely.

Overdosage

No human overdosage data has been reported for this combination inhaler; however data on overdose with both drugs are given below:

Salmeterol: The signs and symptoms of Salmeterol overdose are seizures, angina, hypertension or hypotension, tachycardia, arrhythmias, nervousness, headache,

tremor, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and insomnia. Other signs of overdosage may include hypokalemia and hyperglycemia. Treatment consists of discontinuation of Salmeterol together with appropriate cardio selective beta-blocking agents, which should be used with caution in patients with a history of bronchospasm.

Fluticasone Propionate: Acute inhalation of Fluticasone Propionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days, as verified by plasma cortisol measurements. Chronic overdose of inhaled Fluticasone Propionate may lead to adrenal suppression. Monitoring of adrenal reserve may be necessary. In cases of Fluticasone Propionate overdose this combination inhaler therapy may still be continued at a suitable dosage for symptom control.

Pharmaceutical Precaution

Do not puncture, break or incinerate pressurized canister even when apparently empty.
Avoid storage in direct sunlight or heat.
Store below 30°C.
Keep away from eyes.
Keep away from children.

Package quantities

Seroxyn ® 25/250 Inhaler: Each canister contains 120 metered doses, each actuation delivers Salmeterol Xinafoate INN equivalent to 25 µg Salmeterol and Fluticasone Propionate BP 250 µg.

Seroxyn ® 25/125 Inhaler: Each canister contains 120 metered doses, each actuation delivers Salmeterol Xinafoate INN equivalent to 25 µg Salmeterol and Fluticasone Propionate BP 125 µg.

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