Only for the use of medical professional

Seroxyn® Acucap

Dry Powder Inhaler
Salmeterol Xinafoate and Fluticasone Propionate

Description
Seroxyn® Acucap is a combination of Salmeterol Xinafoate and Fluticasone Propionate. Salmeterol Xinafoate is a selective, long acting β_2 agonist; it attaches to β_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.

Indications
Seroxyn® Acucap is indicated for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting β_2 adrenoceptor agonist) is appropriate and in patients with severe COPD.

Dosage and Administration
Asthma
Adult and Child over 5 years:
- Seroxyn® 50/100 Acucap Inhaler-1 Acucap twice daily.

Adult and Child over 12 years:
- Seroxyn® 50/100 Acucap Inhaler-1 Acucap twice daily.
- Seroxyn® 50/250 Acucap Inhaler-1 Acucap twice daily.
- Seroxyn® 50/500 Acucap Inhaler-1 Acucap twice daily.

COPD
- Seroxyn® 50/250 Acucap Inhaler-1 Acucap twice daily.
- Seroxyn® 50/500 Acucap Inhaler-1 Acucap twice daily.

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 β_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 and oropharyngeal irritation.
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.

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

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.

Pregnancy and lactation
There is insufficient experience of the use of this combination in human pregnancy & lactation. Administration of this combination 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.

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 β 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. 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

Seroxyn® Acucap must not be swallowed and can be used with **any inhaler device**.
Remove Acucap capsule from the blister pack just prior to use, as Acucap exposed to moisture may not tear easily.
Avoid storage in direct sunlight or heat. Store below 30°C. Keep away from children.

Package quantities

Seroxyn® 50/100 Acucap Inhaler: Each box contains 30 capsules in alu-alu blister strips. Each Acucap capsule contains Salmeterol Xinafoate BP equivalent to 50 µg Salmeterol and Fluticasone Propionate BP 100 µg.
Seroxyn® 50/250 Acucap Inhaler: Each box contains 30 capsules in alu-alu blister strips. Each Acucap capsule contains Salmeterol Xinafoate BP equivalent to 50 µg Salmeterol and Fluticasone Propionate BP 250 µg.
Seroxyn® 50/500 Acucap Inhaler: Each box contains 30 capsules in alu-alu blister strips. Each Acucap capsule contains Salmeterol Xinafoate BP equivalent to 50 µg Salmeterol and Fluticasone Propionate BP 500 µg.

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