

SINATIDE

SALMETEROL AND FLUTICASONE PROPIONATE

Compositions:

Sinatide 50/250 Cozycap capsule: Each inhalation capsule contains Salmeterol Xinafoate BP equivalent to Salmeterol 50 mcg and Fluticasone Propionate BP 250 mcg.

Pharmacology:

Sinatide cozycap capsule is a combination of Salmeterol equivalent to Salmeterol Xinafoate BP and Fluticasone Propionate BP, Salmeterol Xinafoate is a selective, long acting beta-2 agonist used in the treatment of asthma and other forms of diffuse airways obstruction. Fluticasone Propionate is a corticosteroid with mainly glucocorticoid activity. Fluticasone Propionate is stated to exert a topical effect on the lungs without systemic effects at usual dose.

Dosage And Administration:

Asthma: Adults and Adolescents (12 years and older): Sinatide 50/250 Cozycap capsule: One Cozycap capsule twice daly. COPD: Adults and Adolescents (12 years and older)Sinatide 50/250 Cozycap capsule: One Cozycap capsule twice daily.

Contraindications:

Sinatide cozycap is contraindicated in patients with a history of hypersensitivity to any of the ingredients.

Warning And Precaution:

Cozycap must not be swallowed. Only to be used with CapHaler. Avoid storage in direct sunlight or heat. Remove Cozycap capsule from the blister pack only immediately before use it in the CapHaler as Cozycap capsule exposed to moisture may not be pierced easily.

Side Effects:

As Sinatide Cozycap 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 angioedema. There have been 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. Salmeteroll Fluticasone Propionate clinical trials: The following undesirable effects were commonly reported:Hoarseness/dysphonia, throat irritation, headache, candidiasis of mouth and throat and palpitations.

Use in Pregnancy and Lactation:

Administration of drugs during pregnancy and lactation should only be considered if the expected benefit of the mother is greater than any possible risk to the foetus or child. There is insufficient experience of the use of Salmeterol Xinafoate and Fluticasone Propionate in

human pregnancy and lactation. There are no data available for human breast milk.

Drug Interaction:

Both non-selective and selective b-blockers should be avoided in patients with asthma, unless they are compelling reasons for their use. Due to the very low plasma concentrations achieved after inhaled dosing clinically significant drug interactions are unlikely. Care should be taken when co-administering known strong CYP3A4 inhibitor (e.g. ketoconazole, ritonavir), as there is potential for increased systemic exposure to Fluticasone Propionate.

Overdosage:

There are no data available from clinical trials on overdose with Sinatide Cozycap.

Storage:

Store in cool (below 30°C) and dry place, protect from light, Keep away from children.

Packing:

Sinatide 50/250 Cozycap capsule: Each box contains 3x10 Inhalation capsules in Alu-Alu blister Pack for use with CapHaler device.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.