

Ticamet[®] Cozycap

Salmeterol Xinafoate BP and Fluticasone Propionate BP

COMPOSITION

Ticamet[®] 100: Each Cozycap contains a combination of Salmeterol 50 mcg, as Salmeterol Xinafoate BP and Fluticasone Propionate BP 100 mcg.

Ticamet[®] 250: Each Cozycap contains a combination of Salmeterol 50 mcg, as Salmeterol Xinafoate BP and Fluticasone Propionate BP 250 mcg.

Ticamet[®] 500: Each Cozycap contains a combination of Salmeterol 50 mcg, as Salmeterol Xinafoate BP and Fluticasone Propionate BP 500 mcg.

INDICATION

Ticamet[®] Cozycap for inhalation is indicated for the long term maintenance treatment of asthma in patient 12 years of age and older i.e. for regular treatment of persistent asthma where use of a combination of inhaled corticosteroid plus a bronchodilator has been found to be appropriate. It is not indicated for the relief of acute bronchospasm.

DOSAGE AND ADMINISTRATION

For patients 12 years of age and older:

The dosage for this age group is one Cozycap inhalation twice daily.

The recommended starting doses are based upon patients' current asthma therapy.

For patients who are not currently on an inhaled corticosteroid, whose disease severity warrants treatment with 2 maintenance therapies, including patients on non-corticosteroid maintenance therapy, the recommended starting dose is one Cozycap twice daily.

For patients on an inhaled corticosteroid the following table provides the recommended starting dose.

Current inhaled daily dose of inhaled corticosteroid		Recommended starting dose
Beclometasone dipropionate	≤ 500 µg 500-1000 µg	Salmeterol 50 µg + Fluticasone 100 µg Salmeterol 50 µg + Fluticasone 250 µg
Budesonide	≤ 400 µg 800-1200 µg	Salmeterol 50 µg + Fluticasone 100 µg Salmeterol 50 µg + Fluticasone 250 µg
Fluticasone propionate	≤ 200 µg 500 µg	Salmeterol 50 µg + Fluticasone 100 µg Salmeterol 50 µg + Fluticasone 250 µg
Triamcenolone acetoneide	≤ 1000 µg 1100-1600 µg	Salmeterol 50 µg + Fluticasone 100 µg Salmeterol 50 µg + Fluticasone 250 µg

Children 4 years and older:

One Cozycap of 50 micrograms Salmeterol and 100 micrograms Fluticasone Propionate twice daily.

COPD: One Cozycap of 50 micrograms Salmeterol and 500 micrograms Fluticasone Propionate twice daily.

Geriatric Use: In studies where geriatric patients (65 years of age or older) have been treated with Salmeterol & Fluticasone propionate inhalation powder, efficacy and safety did not differ from that in younger patients. Consequently, no dosage adjustment is recommended. For all patients it is desirable to titrate to the lowest effective strength after adequate asthma stability is achieved. If symptoms arise in the period between doses, a inhaled short-acting b₂-agonist should be taken for immediate relief. Patients who are receiving this combination twice daily should not use Salmeterol for prevention of exercise-induced bronchospasm or for any other reason. If a previously effective dose regimen fails to provide adequate control of asthma, the therapeutic regimen should be evaluated and additional therapeutic options, e.g. replacing the current strength with a higher strength, adding additional inhaled corticosteroid or initiating oral corticosteroid should be considered.

Rinsing the mouth after each inhalation is advised.

CONTRAINDICATION

Ticamet[®] Cozycap is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Hypersensitivity to any of the ingredients of this preparation contraindicates its use.

SIDE-EFFECT

The common side effects experienced are Respiratory tract infection, Pharyngitis, Sinusitis, Hoarseness/dysphonia, Oral candidiasis, Bronchitis, Headache, Nausea & vomiting, GI discomfort & pain, Diarrhoea and Musculoskeletal pain. These adverse reactions were mostly mild to moderate in severity.

Rare cases of immediate and delayed hypersensitivity reactions, including rash and other rare events of angioedema and bronchospasm, have been reported.

PRECAUTION

1. Cardiovascular effect - No effect on the CVS is usually seen after the administration of this drug at recommended doses. Like all other medications containing sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias and hypertension; in patients with convulsive disorders or thyrotoxicosis.

2. Metabolic and other effect - Beta adrenergic medications may produce significant hypokalemia in some patients. Clinically significant changes in blood glucose and/or serum potassium were seen rarely during clinical studies with the drug at the recommended dose. Since Fluticasone propionate is absorbed into the circulation and can be systematically active at higher doses, the beneficial effects of the drug in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose. It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear in a small number of patients, particularly at higher doses. If such changes occur, the dose of the drug should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

3. Eosinophilic conditions - Physicians should be alert to eosinophilia, vasculitic rash, cardiac complications and/or neuropathy presenting in their patients.

PREGNANCY & LACTATION

The drug should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Fluticasone propionate, another component of the drug, is secreted in human breast milk; however, other corticosteroids have been detected in human milk. Caution should be exercised when the drug is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Cozycap are to be used through revolizerTM only.

Cozycap are not to be swallowed.

Do not exceed the recommended dose.

Store in a cool place away from heat & moisture.

Insert the Cozycap in the revolizerTM just prior to use, as Cozycap exposed to moisture may not break open easily.

Rinsing the mouth after each inhalation is advised.

STORAGE

Should be stored in a cool and dry place, protected from light & moisture.

Keep out of reach of children.

HOW SUPPLIED

Ticamet[®] 100 Cozycap - Each box contains 30 Cozycaps in Alu-Alu Blister pack.

Ticamet[®] 250 Cozycap - Each box contains 48 Cozycaps in Alu-Alu Blister pack.

Ticamet[®] 500 Cozycap - Each box contains 30 Cozycaps in Alu-Alu Blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH