



Salmeterol Xinafoate EP & Fluticasone Propionate BP

Composition:

Ticamet[®] 125 HFA Inhaler: Each single actuation provides 25 micrograms of Salmeterol (as Salmeterol Xinafoate EP) and 125 micrograms of Fluticasone Propionate BP (delivered from the valve).

Ticamet® 250 HFA Inhaler: Each single actuation provides 25 micrograms of Salmeterol (as Salmeterol Xinafoate EP) and 250 micrograms of Fluticasone Propionate BP (delivered from the valve).

Indication:

 ${f Ticamet}^{\&}$ HFA inhaler is indicated in the regular treatment of asthma where use of a

combination product (long-acting $\beta 2$ agonist and inhaled corticosteroid) is appropriate:

- \bullet patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting β_2 agonist or
- \bullet patients already adequately controlled on both inhaled corticosteroid & long-acting β_2 agonist.

Dosage & Administration:

Adults and adolescents 12 years and older:

- Two inhalations of 25 micrograms salmeterol and 125 micrograms fluticasone propionate twice daily, or
- Two inhalations of 25 micrograms salmeterol & 250 micrograms fluticasone propionate twice daily.

Special Group: There is no need to adjust the dose in elderly patients or in those with renal impairment or hepatic impairment.

Precaution:

Ticamet® HFA inhaler should not be used to treat acute asthma symptoms for which a fast and short acting bronchodilator is required. Treatment with **Ticamet**® should not be stopped abruptly. As with all inhaled medication containing corticosteroids, **Ticamet**® should be administered with caution in patients with pulmonary tuberculosis. Rarely, **Ticamet**® may cause cardiac arrhythmias e.g. supraventricular tachycardia, extrasystoles and atrial fibrillation and a mild transient reduction in serum potassium at high therapeutic doses.

Children and adolescents <16years taking high doses of fluticasone propionate (typically 1000 microgram/day) may be at particular risk of systemic effects.

Pregnancy & Lactation:

Administration of **Ticamet**® to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Side-effects:

It contains salmeterol and fluticasone propionate, the type and severity of adverse reactions associated with each of the compounds may be expected. Burning sensation of throat after use may occur in some patients.

Overdose:

There are no data available from clinical trials on overdose with **Ticamet**®, however data on overdose with both drugs are given below: The signs and symptoms of salmeterol overdose are tremor, headache and tachycardia. Acute inhalation of fluticasone propionate doses in excess of those recommended may lead to temporary suppression of adrenal function.

Storage:

Keep out of the reach of children. Store below 30°C protected from direct sunlight and heat. Keep away from contact of eyes. The container should not be punctured, broken or burnt even when apparently empty.

How Supplied:

Ticamet[®] 125 HFA Inhaler: Each Inhaler delivers 120 puffs. Ticamet[®] 250 HFA Inhaler: Each Inhaler delivers 120 puffs.

Manufactured by

