

## Prescribing Information: Fusacomb Easyhaler

### Fusacomb Easyhaler 50 mcg/250 mcg and 50 mcg/500 mcg per dose inhalation powder (salmeterol xinafoate and fluticasone propionate)

**Indication:** Asthma Regular treatment of asthma in patients aged 12 years and above, where use of a combination product (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 corticosteroid and long-acting  $\beta_2$  agonist. **COPD** Adults for the symptomatic treatment of patients with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

**Dosage and Administration:** see SPC for full details on dosing. Inhalation. **Asthma** Adults and adolescents 12 years and older: One inhalation of 50/250 twice daily or one inhalation of 50/500 twice daily. **COPD** Adults: One inhalation of 50/500 twice daily.

#### **Contraindications:**

Hypersensitivity to the active substances or lactose monohydrate (which contains milk proteins).

**Warnings and Precautions:** Not for treatment of acute asthma symptoms. Do not initiate during an exacerbation. Advise patients to seek medical attention if symptoms are uncontrolled or worsen. Do not stop treatment abruptly. Consider reducing the dose once asthma symptoms are controlled; the lowest effective dose should be used. Rinse mouth with water after inhaling to reduce risk of oropharyngeal thrush. Caution in patients with: active or quiescent pulmonary tuberculosis

and fungal, viral or other infections of the airway, severe cardiovascular disorders or heart rhythm abnormalities, have or have a history of diabetes mellitus, thyrotoxicosis, uncorrected hypokalaemia or predisposed to low levels of serum potassium. Paradoxical bronchospasm may occur, treatment should be stopped immediately. Systemic effects may occur, particularly at high doses prescribed for long periods, review patients regularly. Take care when transferring patients with impaired adrenal function from previous systemic steroid therapy. Prolonged treatment with high doses of inhaled steroids may be at risk of impaired adrenocortical function, consider additional systemic corticosteroid during periods of stress. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. In COPD, be vigilant for the possible development of pneumonia. Avoid concomitant treatment with ritonavir, ketoconazole or other potent CYP3A4 inhibitors. Monitor children and adolescents due to an increased risk of systemic side-effects.

**Fertility, pregnancy and lactation:** Balance benefits against risks.

**Undesirable Effects:** Pharmacological side effects of  $\beta_2$  agonist treatment, such as tremor, palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy. *Very Common:* headache, nasopharyngitis. *Common:* candidiasis of the mouth and throat, pneumonia (in COPD patients), bronchitis, hypokalaemia, throat irritation, hoarseness/dyspnoea, sinusitis, contusions, muscle

cramps, traumatic fractures, arthralgia, myalgia. *Uncommon:* cutaneous hyper-sensitivity reactions, dyspnoea, hyperglycaemia, anxiety, sleep disorders, tremor, cataract, palpitations, tachycardia, atrial fibrillation, angina pectoris. *Rare:* oesophageal candidiasis, angioedema, bronchospasm, anaphylactic reactions, Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, behavioural changes, glaucoma, cardiac arrhythmia, decreased bone mineral density. *Not known:* blurred vision, depression, aggression (mainly children). Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Fusacomb Easyhaler 50 mcg/250 mcg: 60 doses, £21.50 PL 27925/0093. Fusacomb Easyhaler 50 mcg/500 mcg, 60 doses, £26.99, PL 27925/0094 **Marketing Authorisation Holder:** Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland. Distributed by Orion Pharma (UK) Ltd, 9th Floor, The Blade, Abbey Square, Reading, RG1 3BE, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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**Job Code:** REF-00868

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Orion Pharma (UK) Ltd on 01635 520300