

INSPIRED TO ACHIEVE



Combisal
Salmeterol/Fluticasone
Meets the ups and downs of
cost-effective asthma management

Flexibility and consistency for
patients and prescribers,
every step of the way.

Combisal® (salmeterol/fluticasone) PRICE GUARANTEE For U.K Healthcare professionals only

Our mission is to work with the NHS to help achieve their efficiency savings goals by offering high quality branded medicines that provide significant cost savings and continuity for patients. *

Combisal® (salmeterol/fluticasone) pressurised metered dose inhaler (pMDI) could save the NHS up to 55% on their current costs, compared with the brand originator.¹

Product	NHS Price ¹ Seretide® (salmeterol/fluticasone) Evohaler	Combisal® NHS Price	Savings vs Seretide®	PIP code	AAH Product code
salmeterol/fluticasone 25µg/50µg pMDI	£17.46	£13.50	23%	407-9075	COM811P
salmeterol/fluticasone 25µg/125µg pMDI	£23.45	£10.48	55%	407-9067	COM813H
salmeterol/fluticasone 25µg/250µg pMDI	£29.32	£13.99	52%	407-9083	COM812L

We confirm that the prices will remain unchanged unless there is a material change to Category C of the UK Drug Tariff or the product in the 2024 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) review.

If you would like any further information, please do not hesitate to contact Aspire Pharma on 01730 231148 or info@aspirepharma.co.uk.

Yours faithfully

Richard Condon
Chief Executive Officer

* Prescribing by brand ensures a single product is dispensed for continuity, rather than a variety of generic products.

References: 1) England and Wales Drug Tariff April 2023

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Combisal (Salmeterol/ Fluticasone) Prescribing Information (please refer to the full SmPC before prescribing)

Indications: Regular treatment of asthma where use of combination product (long-acting β_2 agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 agonist or patients already adequately controlled on both inhaled corticosteroid and long-acting β_2 agonist **Available strengths:** 25 μ g/50 μ g; 25 μ g/125 μ g & 25 μ g/250 μ g salmeterol/fluticasone per metered dose pressurised inhalation, suspension.

Dosage and method of use: Inhalation use. Adults and adolescents 12 years and older: two inhalations twice daily. Children 4 years and older: two inhalations 25 μ g/50 μ g twice daily. Titrate to lowest dose at which effective control of symptoms is maintained and if long-term control maintained at lowest dose, consider testing inhaled corticosteroid alone or combination once daily. Combisal 25 μ g /50 μ g not appropriate for adults and children with severe asthma. Maximum licensed dose of fluticasone propionate in children is 100 μ g twice daily. No data in children under 4 years. AeroChamber Plus[®] spacer device can be used. This may increase drug delivery to lungs with increase in risk of systemic adverse effects. Advise patients to rinse mouth out with water and spit out, and/or brush teeth after each dose of medicine to minimize risk of oropharyngeal candidiasis and hoarseness.

Contraindications: Hypersensitivity to active substance or excipients. **Special warnings and precautions for use:** Do not use to treat acute asthma for which fast-acting short-acting bronchodilator required or initiate Combisal during an exacerbation, or if asthma is significantly worsening or acutely deteriorating. Use with 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, diabetes mellitus, thyrotoxicosis, uncorrected hypokalaemia or predisposed to low levels of serum potassium. Discontinue if paradoxical bronchospasm occurs. Prolonged use of high doses of ICS may result in adrenal suppression and acute adrenal crisis. Consider additional systemic corticosteroid cover during periods of stress or elective surgery. Monitor patients transferring from oral steroids for impaired adrenal reserve. Safety and efficacy in COPD not established. Visual disturbance reported with steroid use – if blurred vision or other visual disturbances, consider referral to ophthalmologist for evaluation of possible

causes e.g. cataract, glaucoma, central serous chorioretinopathy. If prolonged treatment in children, monitor height and ensure dose of inhaled steroid is lowest at which effective asthma control is maintained. **Interactions:** The following combinations should be avoided: Ritonavir, ketoconazole, itraconazole, cobicistat containing products or other potent CYP3A4 inhibitors, moderate CYP3A inhibitors e.g. erythromycin (if benefit outweighs risk, monitor for systemic steroid side effects); non-selective and selective β blockers; xanthine derivatives, steroids and diuretics in acute severe asthma. Other β adrenergic containing drugs can have an additive effect. **Pregnancy & Lactation:** Administer only if expected benefit to mother is greater than any possible risk to fetus. Not to be used during breastfeeding. **Side effects:** For full list of side effects consult SmPC. 'Very Common' 'Common' and 'Serious' side effects included in prescribing information. Very common ($\geq 1/10$) side effects: headache, nasopharyngitis. Common ($\geq 1/100$ to $< 1/10$) side effects: candidiasis of mouth and throat, pneumonia, bronchitis, hypokalaemia, throat irritation, hoarseness/dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia, myalgia. Uncommon Serious ($\geq 1/1000$ to $< 1/100$) side effects: cutaneous hypersensitivity reactions, dyspnoea, hyperglycaemia, anxiety, sleep disorders, tremor, cataract, palpitations, tachycardia, atrial fibrillation, angina pectoris. Rare serious ($\geq 1/10,000$ to $< 1/1000$) side effects: oesophageal candidiasis, facial and oropharyngeal angioedema, bronchospasm, anaphylactic reactions including anaphylactic shock, Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decreased bone mineral density, behavioural changes (psychomotor hyperactivity and irritability predominantly in children), glaucoma, cardiac arrhythmias, paradoxical bronchospasm. Serious side effects (unknown frequency): depression, aggression (predominantly in children), blurred vision. **MA number:** PL 36532/0001-0003. **Cost:** £13.50 for 25/50 μ g, £10.48 for 25/125 μ g, £13.99 for 25/250 μ g. **MAH:** Genetic S.p.A., Via G. Della Monica 26, 84083 Castel San Giorgio (SA), Italy. **Distributed in the UK by:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG. **Legal category:** POM. **Date reviewed:** March 2023 **Version number:** 1010422348 v 7.0

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Aspire Pharma Ltd on 01730 231148.