

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 where use of a combination product (long-acting β_2 agonist and inhaled cortico-steroid) 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. **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.** **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. 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. 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 β_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 hypersensitivity 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: 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, 27925/0094 **Marketing Authorisation Holder:** Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland. Distributed by Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

Date of Prescribing Information: February 2021.

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 Orion Pharma (UK) Ltd on 01635 520300

Prescribing Information: Fobumix Easyhaler

Fobumix Easyhaler 80 micrograms/4.5 micrograms, 160 micrograms/4.5 micrograms and 320 micrograms/9 micrograms, inhalation powder (budesonide and formoterol fumarate dihydrate)

Indication: Fobumix Easyhaler is indicated in adults 18 years and older. **Asthma All strengths:** Regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) is appropriate. **80/4.5:** not appropriate in patients with severe asthma. **COPD 160/4.5 and 320/9:** Symptomatic treatment of patients with COPD with $FEV_1 < 70\%$ predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

Dosage and Administration: Asthma: Not intended for the initial management of asthma. The dosage of the components is individual and should be adjusted to the severity of the disease. **Main-tenance therapy:** **80/4.5 and 160/4.5:**

Adults: 1-2 inhalations twice daily, maximum 4 inhalations twice daily. **320/9:** Adults: 1 inhalation twice daily, maximum 2 inhalations twice daily. **All strengths:** Titration to the lowest effective dose could include once daily use, when a long acting bronchodilator and inhaled corticosteroid would be required to maintain control. Children: not recommended.

Maintenance and reliever therapy: 80/4.5 and 160/4.5 only: Advise patients to always have Fobumix Easyhaler available for rescue use at all times. Monitor closely for dose-related adverse effects in patients who frequently take high numbers of Fobumix Easyhaler as-needed inhalations. Adults: 2 inhalations daily taken as a single or divided dose; for 160/4.5 only, a maintenance dose of 2 inhalations twice daily may be appropriate. Rescue use: 1 additional inhalation as needed in response to symptoms; if symptoms persist after a few minutes, an additional inhalation should be taken, maximum 6 inhalations on any single occasion. A total daily dose of more than 8 inhalations is not normally needed; however, a total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. Children: not recommended.

COPD 160/4.5: Adults: Two inhalations twice daily. **320/9:** Adults: 1 inhalation twice daily. Children: not recommended. **Contraindications:** Hypersensitivity to budesonide, formoterol, lactose or milk proteins.

Warnings and Precautions: Do not initiate during an exacerbation. Advise patients to seek medical advice if asthma symptoms remain uncontrolled or worsen. Do not stop abruptly. Sudden and progressive deterioration in control of asthma or COPD is potentially life threatening, patient should undergo urgent medical assessment. Consider reducing the dose once asthma symptoms are controlled; the lowest effective dose should be used. Not intended for regular prophylactic use, e.g. before exercise. Systemic effects may occur, particularly with high doses prescribed for long periods; consider potential effects on bone density. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. 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. Transfer of patients treated with oral corticosteroids to inhaled corticosteroid and their subsequent management requires special care. Rinse mouth with water after inhaling the maintenance dose to minimise risk of oral symptoms. Avoid concomitant treatment with itraconazole, ritonavir or other potent CYP3A4 inhibitors. Caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, active or quiescent tuberculosis, airways infections, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm, prolongation of the QTc interval or other severe cardiovascular disorders. Potentially serious hypokalaemia may result from high doses of β_2 -adrenoceptor agonists; particular caution in unstable and acute severe asthma, as this effect may be potentiated by hypoxia, and concomitant treatment with xanthine-derivatives, steroids and diuretics; monitor serum potassium levels. In COPD, be vigilant for the possible development of pneumonia. Contains lactose; the amount does not normally cause problems in lactose intolerant people. **Fertility, pregnancy and lactation:** Balance benefits against

risks. **Undesirable Effects:** The most common adverse reactions, such as tremor and palpitations, tend to be mild and usually disappear within a few days of treatment. **Common:** candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in throat, coughing, dysphonia including hoarseness, pneumonia in COPD patients. **Uncommon:** aggression, psychomotor hyperactivity, anxiety, sleep disorders, dizziness, blurred vision, tachycardia, nausea, bruises, muscle cramps. **Other undesirable effects:** Immediate and delayed hypersensitivity reactions (e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction), hypokalaemia, cardiac arrhythmias (e.g. atrial fibrillation, supraventricular tachycardia, extra systoles), bronchospasm, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hyperglycaemia, depression, behavioural changes (predominantly in children), taste disturbance, cataract and glaucoma, angina pectoris, prolongation of QTc interval, variations in blood pressure. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Product Authorisation Numbers:** Fobumix Easyhaler 80/4.5, inhalation powder: 120 actuations, £21.50 PL 27925/0090. Fobumix Easyhaler 160/4.5, inhalation powder: 60 actuations, £10.75, 120 actuations £21.50 PL 27925/0091. Fobumix Easyhaler 320/9, inhalation powder: 60 actuations, £21.50 PL 27925/0092. **Marketing Authorisation Holder:** Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland. Distributed by Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark. **Date of Prescribing Information:** February 2021

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Prescribing Information: Salbutamol Easyhaler

Easyhaler® Salbutamol Sulfate 100 micrograms and 200 micrograms per actuation inhalation powder (salbutamol sulfate)

Indication: Symptomatic treatment of asthma attacks and exacerbations of asthma in adults and children aged 4 years and over; prevention of exercise-induced bronchospasm or before unavoidable allergen exposure; symptomatic treatment of bronchoasthma and other conditions associated with reversible airways obstruction. **Dosage and administration:** *Adults, older people and children aged 12 years and over:* 100 and 200 mcg -

Bronchospasm and intermittent episodes of asthma, 100-200mcg as a single dose, increasing to 200-400mcg if necessary. To prevent exercise or allergen induced bronchospasm, 200mcg before challenge, repeated if necessary. *Children aged 4-11 years:* 100-200 mcg for relief of acute bronchospasm, or before exercise or allergen exposure. Chronic therapy, 200mcg four times a day. On demand use should not exceed 800 mcg in 24 hours **Contraindications:**

Hypersensitivity to salbutamol, lactose or milk proteins. Not for management of premature labour or threatened abortion. **Warnings and Precautions:**

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma; consider using oral corticosteroid or the maximum use of inhaled corticosteroids. If treatment fails to give relief for at least three hours or

more inhalations are needed than usual, medical attention should be sought. Regular anti-inflammatory therapy is required if inhaled beta-agonists are needed more than twice a week. Dosage and frequency of administration should only be increased on medical advice. Caution in patients with thyrotoxicosis, cardiac insufficiency, hypokalaemia, myocardial ischaemia, tachyarrhythmia and hypertrophic obstructive cardiomyopathy or using additional adrenergic drugs. Particular caution in acute severe asthma, as hypokalaemia may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and hypoxia. Cardiovascular effects may be seen. Concomitant use with non-selective beta-blocking drugs are not recommended. Patients with underlying severe heart disease should seek medical advice if they experience chest pain or other cardiac symptoms. Salbutamol can induce reversible metabolic changes such as increased blood glucose. Diabetic patients should be monitored. Assess symptoms such as dyspnoea and chest pain as they may be of respiratory or cardiac origin. Monitor initial concomitant use with monoamine oxidase inhibitors or tricyclic anti-depressants. Not suitable for patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose

malabsorption. **Fertility, pregnancy and lactation:** Balance benefits against risks. **Undesirable effects:** *Common:* Palpitations, peripheral vasodilatation, and as a result small increase in heart rate, tremor. *Uncommon:* headache, hypersensitivity reactions hypotension and collapse. *Serious undesirable effects include:* hypokalaemia, bronchospasm, myocardial ischaemia, cardiac arrhythmias Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Presentation, cost and marketing authorisation number:** Easyhaler Salbutamol Sulfate 100 micrograms per actuation inhalation powder; 200 actuations £3.31 PL 27925/0002. Easyhaler Salbutamol Sulfate 200 micrograms per actuation inhalation powder 200 actuations, £6.63 PL 27925/0003 **Distributed by** Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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Prescribing Information: Formoterol Easyhaler

Formoterol Easyhaler® 12 micrograms/dose inhalation powder (formoterol fumarate dihydrate)

Indication: Treatment of asthma in patients treated with inhaled corticosteroids and who also require a long-acting beta₂-agonist; relief of reversible airways obstruction in patients with COPD needing long-term bronchodilators. **Dosage and administration:** *Adults, older people and adolescents over 12 years: Asthma* - One inhalation twice daily, increasing to a maximum of two inhalations twice daily if necessary. *COPD* - One inhalation twice daily. *Children 6-12 years: Asthma* - One inhalation twice daily. Maximum 24mcg daily. Not recommended in children under the age of 6. *Renal and hepatic impairment:* No data. Increased exposure expected in severe liver cirrhosis.

Contraindications: Hypersensitivity to formoterol, lactose or milk proteins. **Warnings and Precautions:** Should not be used as first treatment for asthma. Patients with asthma should receive optimal maintenance therapy with corticosteroids and must be advised to continue this even if symptoms decrease. Reassess if symptoms persist. Do not initiate during an acute exacerbation. Consider reducing the dose once symptoms are controlled; the lowest effective dose should be used. Frequent need of medication for pre-vention of exercise-induced broncho-constriction

despite adequate maintenance treatment warrants reassessment. Caution in patients with severe hypertension, severe heart failure, ischaemic heart disease, cardiac arrhythmias, idiopathic subvalvular aortic stenosis, hypertrophic obstructive cardiomyopathy, thyrotoxicosis, phaeochromocytoma, aneurysm, known or suspected prolongation of the QTc interval and in patients treated with drugs affecting the QTc interval. Caution in use with theophylline in patients with cardiac conditions. Additional blood glucose controls recommended for diabetic patients. Potentially serious hypokalaemia may result from beta₂-agonist therapy; particular caution in acute severe asthma, as this effect may be potentiated by hypoxia and concomitant treatment with xanthine derivatives, steroids, diuretics. Monitor serum potassium levels. Paradoxical bronchospasm may occur. Not suitable for patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Fertility, pregnancy and lactation:** Balance benefits against risks. **Undesirable effects:** Most commonly reported adverse events, such as tremor, palpitations and headache, tend to be mild and disappear within a few days of treatment. *Uncommon:* Agitation, restlessness, anxiety,

sleep disturbances, muscle cramps, myalgia, tachycardia. *Serious undesirable effects:* Hypersensitivity reactions such as bronchospasm, severe hypotension, urticaria, angioedema, pruritus, exanthema, peripheral oedema, hypokalaemia, cardiac arrhythmias e.g. atrial fibrillation, supraventricular tachycardia, extrasystoles, aggravated bronchospasm, paradoxical bronchospasm, oropharyngeal irritation, nausea, hyperglycaemia, angina pectoris, prolongation of QTc interval, variation in blood pressure. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Presentation, cost and marketing authorisation number:** Formoterol Easyhaler 12 micrograms per actuation inhalation powder containing 120 actuations, £23.75 PL 27925/0050. **Distributed by** Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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Prescribing Information: Budesonide Easyhaler

Easyhaler® Budesonide 100 micrograms, 200 micrograms and 400 micrograms/dose inhalation powder (budesonide)

Indication: Treatment of mild, moderate or severe persistent asthma. **Dosage:** Adjust according to individual patient need including transfer from other inhaler devices. *Mild asthma:* Adults (including the elderly and adolescents 12-17 years) and for children 6-11 years: 200-400 mcg/day, up to 800 mcg/day in two divided doses. *Moderate and severe asthma:* Adults: up to 1600 mcg/day. *Maintenance dose:* Twice daily dosing adults: 100-400 mcg twice daily. During periods of severe asthma, daily dose may be increased up to 1600 mcg in two divided doses and reduced when asthma has stabilised. Children aged 6-11 years: 100-200 mcg twice daily up to 800 mcg in two doses. Reduce dose when asthma has stabilised. *Once daily dosing in mild to moderate asthma:* In steroid naïve patients: 200-400 mcg. In patients already controlled on inhaled corticosteroids: up to 800 mcg, children aged 6-11 years: 200-400 mcg. Take once daily dose in the evening. **Contraindications:** Hypersensitivity to budesonide, lactose or milk proteins. **Warnings and precautions:** Not for treatment of acute dyspnoea or status asthmaticus. Must be used regularly and should not be stopped abruptly. Patients who have used high dose emergency steroid therapy or prolonged treatment with high doses of inhaled steroids may be at risk of impaired

adrenocortical function and may need supplementary systemic corticosteroid during periods of stress. Transfer of patients treated with oral corticosteroids to the inhaled corticosteroid and their subsequent management requires special care. Paradoxical bronchospasm may occur. Systemic effects may occur with high doses; titrate dose to lowest effective level. Monitor height of children receiving prolonged treatment. Reduced liver function affects the elimination of corticosteroids. Avoid concomitant cobicistat, HIV protease inhibitors or other potent CYP3A4 inhibitors, if benefit outweighs risk, monitor for systemic corticosteroid side effects. Refer patients with blurred vision or other visual disturbances to an ophthalmologist. Rinse mouth with water or brush teeth after inhaling to minimise risk of oral symptoms. Not suitable for patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption. **Fertility, pregnancy and lactation:** Balance benefits against risks. **Undesirable effects:** *Common:* Cough and throat irritation, oropharyngeal candidiasis, difficulty in swallowing. *Uncommon:* anxiety, depression, cataract, blurred vision, muscle spasm, tremor. *Serious undesirable effects include:* Hypersensitivity reactions including angioedema and anaphylactic reaction,

hypocorticism, hypercorticism, adrenal suppression, growth retardation, behavioural changes (mainly in children), bronchospasm, pruritus, erythema, bruising, glaucoma, decreased bone density, psychomotor hyperactivity, sleep disorders, aggression, psychosis. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Presentation, cost and marketing authorisation number:** Easyhaler Budesonide 100 micrograms per actuation inhalation powder: 200 actuations, £8.86 PL 27925/0008. Easyhaler Budesonide 200 micrograms per actuation inhalation powder: 200 actuations, £17.71 PL 27925/0009. Easyhaler Budesonide 400 micrograms per actuation inhalation powder: 100 actuations, £17.71 PL 27925/0010. **Distributed by** Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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Prescribing Information: Beclometasone Easyhaler

Easyhaler® Beclometasone 200 micrograms/dose inhalation powder (beclometasone dipropionate)

Indication: Prophylactic management of mild, moderate, or severe asthma in adults. **Dosage and administration:** Oral inhalation. Starting dose should be appropriate to the severity of disease. Dose may be adjusted until control is achieved, or reduced to minimum effective dose according to individual response. *Adults (including older people):* Usual starting dose 200 micrograms twice a day, up to 600 to 800 micrograms per day in more severe cases. Total daily dose may be administered as two, three, or four divided doses. *Children:* Not recommended. **Contraindications:** Hypersensitivity to beclometasone, lactose or milk proteins. Special care in patients with active or quiescent pulmonary tuberculosis. **Warnings and precautions:** Ensure patient has correct inhaler technique and understands prophylactic nature of therapy. Not for relief of acute asthma symptoms; advise patients to have rescue medication available. Regularly assess patients with severe asthma. Increasing use of bronchodilators indicates deterioration of asthma control; consider increasing anti-

inflammatory therapy. Systemic effects may occur; titrate dose to lowest effective level. Monitor height of children receiving prolonged treatment. Patients transferred from oral steroids should be monitored regularly and their dose of systemic steroid reduced cautiously. Treatment should not be stopped abruptly. Care is needed in pulmonary tuberculosis. Caution and monitoring with concomitant strong CYP3A inhibitors. Not suitable for patients with galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption. **Fertility, pregnancy and lactation:** Balance benefits against risks. **Undesirable effects:** *Very common* - Oropharyngeal candidiasis. *Common:* Hoarseness, throat irritation, cough. *Uncommon:* Hypersensitivity reactions with rash, urticaria, pruritus, erythema. *Serious undesirable effects:* Hypersensitivity reactions with oedema of the eyes, face, lips and throat, respiratory symptoms and anaphylactoid/anaphylactic reactions. Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation

in children and adolescents, decrease in bone mineral density, cataract, glaucoma, paradoxical bronchospasm, psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children), eosinophilic pneumonia, easy bruising, skin thinning. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM **Presentation, cost and marketing authorisation number:** Easyhaler Beclometasone 200 micrograms/dose inhalation powder containing 200 actuations, £14.93 PL 27925/0001. **Distributed by** Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, UK. Full prescribing information is available on request. Easyhaler is a registered trademark.

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