# Abbreviated Prescribing Information: WockAIR 160mcg/4.5mcg and 320mcg/9mcg Inhalation Powder, Predispensed

(160mcg budesonide and 4.5mcg formoterol fumarate dihydrate; 320 mcg budesonide and 9mcg formoterol fumarate dihydrate). Please refer to the Summary of Product Characteristics (SmPC) before prescribing

**Presentation:** WockAIR Inhaler contains 60 doses of powder medicinal product in a coiled strip of foil with a dose counter and should be disposed of when empty and replaced with a new one.

**Indications:** In adults and adolescents (12 years and older) for the regular treatment of asthma where use of combination (inhaled corticosteroids and long-acting $\beta_2$ adenoreceptor agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting $\beta_2$ adrenoceptor agonists or patients already adequately controlled on both inhaled corticosteroids and long-acting $\beta_2$ adrenoceptor agonists. WockAIR 160/4.5mcg is also indicated as reliever therapy for adults and adolescents (12 years and older) with mild asthma. WockAIR is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with FEV1 <70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

**Dosage and Administration:** For the treatment of asthma, the required dose of each component of WockAIR is individual and should be adjusted to the severity of the disease. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. WockAIR is not recommended for children younger than 12 years. ***Maintenance therapy***: adults (18 years and older): 1-2 inhalations twice daily. Some patients may require up to a maximum of 4 inhalations twice daily; adolescents (12 – 17 years): 1-2 inhalations twice daily. ***Maintenance and reliever therapy***: adults and adolescents (12 years and older): 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening. Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. ***Reliever therapy***: Adults and adolescents (12 years and older): Patients should take 1 inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. 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 and should be reassessed. ***COPD***: adults: 2 inhalations twice daily. Patients should be demonstrated how to use the WockAIR inhaler and correct use should be checked regularly.

**Contraindications:** Hypersensitivity to the active substances or to any of the excipients.

**Warnings and Precautions:** Patients should be advised to have their rescue inhaler available at all times. Serious asthma-related adverse events and exacerbations may occur during treatment with WockAIR. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation with WockAIR. If patients find the treatment ineffective, or exceed the highest recommended dose of WockAIR, medical attention must be sought. Patients should not be initiated on WockAIR during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Paradoxical bronchospasm may occur, with an immediate increase in wheezing and shortness of breath, after dosing and WockAIR should be discontinued immediately. Systemic effects may occur with any inhaled corticosteroid, including Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression. WockAIR should be administered with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Caution should be observed when treating patients with prolongation of the QTc-interval since Formoterol itself may induce QTc-interval prolongation. Concomitant treatment of β2 adrenoceptor agonists with medicinal products which can induce hypokalaemia or potentiate a hypokalaemic effect, e.g. xanthine derivatives, steroids and diuretics, may add to a possible hypokalaemic effect of the β2 adrenoceptor agonist. Visual disturbance may be reported with systemic and topical corticosteroid use and patient should be considered for evaluation of possible causes (e.g. cataract, glaucoma or central serous chorioretinopathy). WockAIR contains lactose monohydrate and may cause allergic reactions. In children, height should be regularly monitored to identify possible growth retardation. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of inhaled corticosteroid to the lowest dose at which effective control of asthma is maintained. An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids.

**Drug interactions:** Potent inhibitors of CYP3A4 (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, telithromycin, nefazodone, cobicistat and HIV protease inhibitors) are likely to markedly increase plasma levels of budesonide and WockAIR maintenance and reliever therapy is not recommended. Beta-adrenergic blockers can weaken or inhibit the

effect of formoterol. WockAIR should therefore not be given together with beta-adrenergic blockers (including eye drops). Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine) and tricyclic antidepressants can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards β2 sympathomimetics. Concomitant treatment with monoamine oxidase inhibitors, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertensive reactions. There is an elevated risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons. Concomitant use of other beta-adrenergic or anticholinergic medicinal products can have a potentially additive bronchodilating effect. Hypokalaemia may result from beta2-agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, corticosteroids and diuretics and may increase the disposition towards arrhythmias in patients who are treated with digitalis glycosides.

**Pregnancy and lactation:** For budesonide/formoterol or the concomitant treatment with formoterol and budesonide, no clinical data on exposed pregnancies are available. There are no adequate data from use of formoterol in pregnant women. Data on approximately 2000 exposed pregnancies indicate no increased teratogenic risk associated with the use of inhaled budesonide. During pregnancy, WockAIR should only be used when the benefits outweigh the potential risks at the lowest effective dose. Budesonide is excreted in breast milk. Administration of WockAIR to women who are breast-feeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child. There is no data available on the potential effect of budesonide on fertility.

**Undesirable effects:** The following adverse events were reported in clinical practice: ***Common***: candida infections in the oropharynx, pneumonia (in COPD patients), headache, tremor, palpitations, mild irritation in the throat, coughing, dysphonia including hoarseness; ***Uncommon***: aggression, psychomotor hyperactivity, anxiety, sleep disorders, dizziness, blurred vision, tachycardia, nausea, bruises, muscle cramps; ***Rare***: immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction, hypokalaemia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia, extrasystoles, bronchospasm; ***Very rare***: Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hyperglycaemia, depression, behavioural changes (predominantly in children), taste disturbances, cataract and glaucoma, angina pectoris, prolongation of QTc-interval, variations in blood pressure. For further information on adverse effects please refer to the SmPC.

**Legal Category:** POM **Marketing Authorization Number and Holder:** Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

**Marketing Authorization Number:** PL 29831/0736-0737

**Package quantities and basic NHS price:** 160mcg/4.5mcg: £19.00; 320mcg/9mcg £19.00
**Date of API Preparation:** 17 March 2024

**Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Wockhardt UK Ltd by calling: +44 (0) 1978 669272 or email drug.safety@wockhardt.co.uk**