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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of the Prescribing Information.

GoResp® Digihaler® (budesonide/formoterol) 160mcg/4.5mcg inhalation powder and GoResp Digihaler (budesonide/formoterol) 320mcg/9mcg inhalation powder Abbreviated Prescribing Information. **Presentation:** GoResp Digihaler is an integrated e-connected dry powder inhaler with an accompanying Digihaler companion app for patients and dashboard for healthcare professionals. *GoResp Digihaler 160/4.5mcg*: Each delivered dose contains 160mcg of budesonide and 4.5mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200mcg budesonide and 6mcg of formoterol fumarate dihydrate. *GoResp Digihaler 320/9mcg*: Each delivered dose contains 320mcg of budesonide and 9mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400mcg budesonide and 12mcg of formoterol fumarate dihydrate. Inhalation powder. **Indications:** In the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2-adrenoceptor agonist) is appropriate. This is also indicated in the symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV_1) < 70% predicted normal (post bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For inhalation use only. For use in adults (18 years of age and older only) for asthma, and COPD. ***Asthma*:** Not intended for the initial management of asthma and not appropriate for adult patients with only mild asthma. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. GoResp Digihaler 160/4.5mcg may be used as a maintenance therapy or as a maintenance and reliver therapy. GoResp Digihaler 320/9mcg should be used as maintenance therapy only. *GoResp Digihaler 160/4.5mcg Maintenance therapy - Adults (18 years and older)*: 1-2 inhalations twice daily (up to a maximum of 4 inhalations twice daily). *GoResp Digihaler 160/4.5mcg Maintenance and Reliever Therapy - Adults (18 years and older)*: 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. 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. *GoResp Digihaler 320/9mcg Maintenance therapy - Adults (18 years and older)*: 1 inhalation twice daily. Some patients may require up to a maximum of 2 inhalations twice daily. ***COPD*:** *GoResp Digihaler 160/4.5mcg – Adults*: 2 inhalations twice daily. *GoResp Digihaler 320/9mcg - Adults*: 1 inhalation twice daily. *Elderly patients (≥65 years old)*: No special requirements. *Patients with renal or hepatic impairment*: No data available. GoResp Digihaler is not suitable for use in patients under 18 years of age. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If treatment is ineffective, or exceeds the highest recommended dose, medical attention must be sought. Patients with sudden and progressive deterioration in control of asthma or COPD should undergo urgent medical assessment. Patients should have their rescue inhaler available at all times. The reliever inhalations should be taken in response to symptoms and are not intended for regular prophylactic use e.g. before exercise. Patients should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen, patients should continue treatment and seek medical advice. If paradoxical bronchospasm occurs, treatment should be discontinued immediately. Paradoxical bronchospasm responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Visual disturbance may be reported with systemic and topical corticosteroid use. Such patients should be considered for referral to an ophthalmologist for evaluation of possible causes. Systemic effects may occur, particularly at high doses prescribed for long periods. Potential effects on bone density should be considered, particularly in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress. Treatment should not be stopped abruptly – tapering of dose is recommended. Transfer from oral steroid therapy to a budesonide/formoterol fumarate fixed-dose combination may result in the appearance of allergic or arthritic symptoms which will require treatment. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal Candida infection patients should rinse mouth with water after inhaling the dose. Administer with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. The need for, and dose of inhaled corticosteroids should be re-evaluated in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Additional blood glucose controls should be considered in diabetic patients. Potentially serious hypokalaemia may occur at high doses. Particular caution is recommended in unstable or acute severe asthma. Serum potassium levels should be monitored in these patients. As with other lactose containing products the small amounts of milk proteins

present may cause allergic reactions. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. **Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Co-treatment with CYP3A inhibitors, including cobicistat-containing products is expected to increase risk of systemic side effects and the use in combination should be avoided. Not recommended with β-adrenergic blockers (including eye drops) unless compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), and Tricyclic Antidepressants (TCAs) can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant treatment with monoamine oxidase inhibitors, including agents with similar properties, may precipitate hypertensive reactions. Patients receiving anaesthesia with halogenated hydrocarbons have an elevated risk of arrhythmias. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Pregnancy and lactation:** Use only when benefits outweigh potential risks. Budesonide is excreted in breast milk; at therapeutic doses no effects on the suckling child are anticipated. **Effects on ability to drive and use machines:** No or negligible influence.

Adverse reactions: Since GoResp Digihaler contains both budesonide and formoterol, the same pattern of adverse reactions as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. *Serious*: Immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction, Cushing´s syndrome, adrenal suppression, growth retardation, hypokalaemia, cataract and glaucoma, tachycardia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles, angina pectoris, prolongation of QTc-interval. *Common:* Candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in the throat, coughing, dysphonia including hoarseness. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose of formoterol may lead to: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. **Price per pack:** GoResp Digihaler 160/4.5mcg and GoResp Digihaler 320/9mcg: £75.63. **Legal Category:** POM. **Marketing Authorisation Numbers:** GoResp Digihaler 160/4.5mcg: PLGB 00289/2501. GoResp Digihaler 320/9mcg: PLGB 00289/2502. **Marketing Authorisation Holder/Business Responsible for Sale or Supply:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00207. **Date of Preparation:** June 2023.