

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

DuoResp[®] Spiromax[®] (budesonide/formoterol) 160mcg/4.5mcg inhalation powder and DuoResp[®] Spiromax[®] (budesonide/formoterol) 320mcg/9mcg inhalation powder Abbreviated Prescribing Information. **Presentation:** DuoResp[®] Spiromax[®] 160/4.5: 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. DuoResp[®] Spiromax[®] 320/9: 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:** Asthma: In adults and adolescents (12 years and older) for the treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2 -adrenoceptor agonist) is appropriate. COPD: In adults aged 18 years and older for the symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV₁) < 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:** *Asthma:* Not intended for the initial management of asthma. Not appropriate for patients with only mild asthma.. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of β_2 -adrenoceptor agonists and/or corticosteroids by individual inhalers should be prescribed. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. DuoResp[®] Spiromax[®] 160/4.5: maintenance therapy - regular maintenance treatment with a separate reliever inhaler: *Adults:* 1-2 inhalations twice daily (maximum of 4 inhalations twice daily). *Adolescents (12 years and older):* 1-2 inhalations twice daily. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. DuoResp[®] Spiromax[®] maintenance and reliever therapy - regular maintenance treatment and as needed in response to symptoms: should be considered for patients with: (i) inadequate asthma control and in frequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. *Adults:* The recommended maintenance dose for adults and adolescents (12 years and older) is 2 inhalations per day, given either as one inhalation

morning and evening or as 2 inhalations in either the morning or evening. For some patients a maintenance dose of 2 inhalations twice daily may be appropriate. 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. DuoResp[®] Spiromax[®] 320/9: Only to be used as maintenance therapy. *Adults:* 1 inhalation twice daily (maximum of 2 inhalations twice daily). *COPD: Adults:* 1 inhalation twice daily. *Adolescents (12 years and older):* 1 inhalation twice daily. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. *Elderly patients (≥ 65 years old):* No special requirements. *Patients with renal or hepatic impairment:* No data available. *Paediatric population:* Not recommended for use in children under the age of 12 years. **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. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. 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. 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. Administer with caution in patients with thyrotoxicosis, pheochromocytoma, 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. 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 MAOIs, 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 infants are anticipated. **Effects on ability to drive and use machines:** No or negligible influence. **Adverse reactions:** Since *DuoResp*[®] *Spiromax*[®] 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, decrease in bone mineral density, hypokalaemia, hyperglycaemia, aggression, psychomotor hyperactivity, anxiety, sleep disorders, depression, behavioural changes, cataract and glaucoma, tachycardia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles, angina pectoris, prolongation of QTc-interval, variations in blood pressure, bronchospasm, pneumonia in COPD patients and paradoxical bronchospasm. **Common:** *Candida* infections in the oropharynx, headache, tremor, palpitations, mild irritation in the throat, coughing, pneumonia in COPD patients, 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. **Legal Category:** POM. **Marketing Authorisation Numbers:** *DuoResp*[®] *Spiromax*[®] 160/4.5: EU/1/14/920/001. *DuoResp*[®] *Spiromax*[®] 320/9: EU/1/14/920/004. **Marketing Authorisation Holder:** Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, The Netherlands. **Job Code:** MED-IE-00034. **Date of Preparation:** June 2021.