DuoResp® Spiromax®

budesonide/formoterol

Manufactured in Waterford

3 SIMPLE STEPS:
OPEN, BREATHE, CLOSE[2]

[4]Suitable for Maintenance & Reliever Therapy, 160/4.5mcg strength only

MEDICAL DESIGN EXCELLENCE AWARDS[1] 2015 SILVER WINNER

THE EFFECTIVE COMBINATION OF DRUGS YOU KNOW*
BUDESONIDE / FORMOTEROL

Delivered Dose:[2*]	160/4.5 mcg	320/9mcg
Metered Dose:[2]	200/6 mcg	400/12mcg

DuoResp Spiromax is licensed for use in adults 18 years of age and older only.
*The label on DuoResp Spiromax indicates delivered dose.

75% of asthma and COPD patients considered Spiromax to be intuitive[3]

87% of HCP's considered Spiromax to be intuitive[3]

DuoResp® Spiromax® (budesonide/formoterol fumarate dihydrate) 160 mcg/4.5 mcg inhalation powder and DuoResp® Spiromax® (budesonide/formoterol fumarate dihydrate) 320 mcg/9 mcg inhalation powder

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

Presentation: *DuoResp® Spiromax® 160/4.5:* Each delivered dose contains 160 mcg of budesonide and 4.5 mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200 mcg budesonide and 6 mcg of formoterol fumarate dihydrate. *DuoResp® Spiromax® 320/9:* Each delivered dose contains 320 mcg of budesonide and 9 mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400 mcg budesonide and 12 mcg of formoterol fumarate dihydrate. Inhalation powder. **Indications:** *Asthma:* regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2-adrenoceptor agonist) is appropriate. *COPD:* symptomatic treatment of patients with COPD (FEV$_1$ <70% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For use in adults ≥18 years. Not for use in children <18 years of age. Inhalation use. ***Asthma:*** Not intended for the initial management. Adjust dose according to the individual and the severity of the disease. 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. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. *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). *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 infrequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. *Adults:* The recommended maintenance dose 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:* 2 inhalations twice daily (*DuoResp® Spiromax® 160/4.5*), or 1 inhalation twice daily (*DuoResp® Spiromax® 320/9*). *Elderly patients (≥65 years old):* No special dosing requirements. *Patients with renal or hepatic impairment:* No data available. **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. Patients should not be initiated during an exacerbation or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment. 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. Systemic effects may occur, particularly at high doses prescribed for long periods. Visual disturbance may be reported with systemic and topical corticosteroid use. 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 after inhaling the dose. An increase in the incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids. 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. 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. **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. Avoid co-treatment with CYP3A inhibitors, including cobicistat-containing products (consider risks/benefits). Not recommended with β-adrenergic blockers (including eye drops) unless there are 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 concomitant anaesthesia with halogenated hydrocarbons have an elevated risk of arrhythmias. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Fertility, pregnancy and lactation:** Use only when benefits outweigh potential risks. No data available on the potential effect of budesonide on fertility. Animal reproduction studies with formoterol have shown a somewhat reduced fertility in male rats at high systemic exposure. **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 and paradoxical bronchospasm. *Common: Candida* infections in the oropharynx, pneumonia (in COPD patients), headache, tremor, palpitations, mild irritation in the throat, coughing and 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:** Medicinal product subject to medical prescription. **Marketing Authorisation Number:** *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. **Full prescribing information available from:** Teva Pharmaceuticals Ireland, Floor 1, Wing A, Building 1, Finnabair Business & Technology Park, Dundalk, Co. Louth, Telephone: 1800 201 700. **Date of Preparation:** May 2017. **Job Code:** IE/DUOSP/14/0002(3).

Date of Preparation: December 2017. **Job Code:** IE/DUOSP/17/0011

References
1. Medical Design Excellence Awards 2015/ drug delivery devices/ combination products. 2.DuoResp Spiromax Summary of Product Characteristics .
3. Plusa T, Bijos P. Int Rev Allergol Clin Immunol Family Med 2015; 21: 21-4.

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Respiratory