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

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<th>DuoResp® Spiromax® (budesonide/formoterol)</th>
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<tr>
<td>160mcg/4.5mcg inhalation powder and DuoResp® Spiromax® (budesonide/formoterol) 320mcg/9mcg inhalation powder</td>
<td>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: Treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β₂-adrenoceptor agonist) is appropriate. COPD: Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV₁) &lt; 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 use in adults ≥18 years. Not for use in children &lt; 18 years of age. Asthma: Not intended for the initial management. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of β₂-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). DuoResp® Spiromax® maintenance and reliever therapy: For patients taking DuoResp as reliever, preventative use of DuoResp Spiromax for allergen or exercise-induced bronchoconstriction should take into consideration the frequency of need. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. 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 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. Elderly patients (≥65 years old): No special 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. The reliever inhalations should be taken in response to symptoms and are not intended for regular prophylactic use e.g. before exercise. For such, a separate rapid-acting bronchodilator should be considered. 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 bronchodilator and should be treated straightforward. 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</td>
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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. 

**Price per pack:** DuoResp® Spiromax® 160/4.5 and DuoResp® Spiromax® 320/9: £27.97. 

**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:** DUOR-GB-00002. 

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