**Drug name**

DuoResp Spiromax® 160 µg/4.5 µg and 320 µg/9 µg inhalation powder

**Indications**

- DuoResp Spiromax® is indicated in adults 18 years of age and older only.¹ ²

**Asthma**

- DuoResp Spiromax® is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid [ICS] and long-acting β₂ adrenoceptor agonist [LABA]) is appropriate:¹ ²
  - in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting β₂ adrenoceptor agonists or
  - in patients already adequately controlled on both inhaled corticosteroids and long-acting β₂ adrenoceptor agonists.

**COPD**

- Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV₁) < 70% predicted normal and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.¹ ²

**Dosage**

- Dosage recommendations for DuoResp Spiromax® are dependent on strength and indication. Please refer to the respective summary of product characteristics for full dosage information.¹ ²

- The NHS dictionary of medicines and devices lists DuoResp Spiromax® as an interchangeable product to Symbicort (budesonide and formoterol) Turbohaler® against the metered dose, but recommends not to prescribe either product generically as an interchangeable product to Symbicort Spiromax® and by Symbicort Turbohaler® in terms of efficacy and tolerability, and the products have been shown to be therapeutically equivalent to Symbicort Spiromax® in terms of efficacy and tolerability, and the products have been shown to be therapeutically equivalent to Symbicort Turbohaler® in terms of efficacy and tolerability, and had a similar safety profile.⁴

- Doses are therapeutically equivalent to Symbicort (budesonide and formoterol) Turbohaler®.⁴ ⁵

<table>
<thead>
<tr>
<th>Product</th>
<th>Delivered dose (µg)</th>
<th>Metered dose (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DuoResp Spiromax*</td>
<td>160/4.5</td>
<td>200/6</td>
</tr>
<tr>
<td>Symbicort Turbohaler®</td>
<td>160/4.5</td>
<td>200/6</td>
</tr>
<tr>
<td>DuoResp Spiromax*</td>
<td>320/9</td>
<td>400/12</td>
</tr>
<tr>
<td>Symbicort Turbohaler®</td>
<td>320/9</td>
<td>400/12</td>
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</tbody>
</table>

**Mode of action**

- DuoResp Spiromax® contains budesonide and formoterol, which have different modes of action and show additive effects in terms of reduction of asthma exacerbations. The specific properties of budesonide and formoterol allow the combination to be used either as maintenance and reliever therapy (160/4.5 µg dose only), or as maintenance treatment of asthma.¹

**Guideline recommendations**

**BTS/SIGN**

- Combination inhalers are recommended to:⁶
  - guarantee that LABA is not taken without inhaled corticosteroid
  - improve inhaler adherence

- In adult patients requiring initial add-on therapy due to insufficient control from regular low-dose ICS preventer treatment, the BTS/SIGN asthma guideline recommends the addition of a LABA to ICS (usually in a combination inhaler) to improve control.⁶

**Evidence for use**

- In an open-label, single dose, randomised, 5-way crossover study that evaluated the comparative pharmacokinetics (PK) and safety of budesonide plus formoterol (BF) administered as two inhalations via DuoResp Spiromax® and via Symbicort Turbohaler® in 87 healthy volunteers (HV), DuoResp Spiromax® demonstrated therapeutic equivalence to Symbicort Turbohaler® in terms of efficacy and tolerability, and had a similar safety profile.⁴

- In a single-centre, double-blind, double-dummy, cumulative dose, 4-period crossover study to evaluate the pharmacodynamic (PD) effects of BF administered as cumulative delivered doses by DuoResp Spiromax® and by Symbicort Turbohaler® in 52 HV, the PD effects of BF Spiromax and BF Turbohaler at corresponding strengths were bioequivalent. Both treatments were also well tolerated and the safety profile between them similar.⁶

- In a phase 3b, 12-week, multicentre (17 countries; 120 centres), randomised, double-blind, double-dummy, active-controlled, parallel-group study comparing BF administered via Spiromax and Turbohaler in 605 patients:⁶
  - DuoResp Spiromax® was found to be non-inferior to Symbicort Turbohaler® in relation to efficacy in the treatment of asthma
  - there were no apparent differences between DuoResp Spiromax® and Symbicort Turbohaler® in safety and tolerability.

**Precautions and side-effects**

- DuoResp Spiromax® is contraindicated in cases of hypersensitivity to the active substances or lactose monohydrate.¹

- Since DuoResp Spiromax® contains budesonide and formoterol, the same pattern of adverse reactions as reported for these substances is expected.

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This formulary decision guide was developed from content provided by Teva UK Limited in a format developed by Guidelines in Practice. It has been reviewed by a member of the Guidelines in Practice editorial board.

Abbreviated prescribing information can be found overleaf.

**UK/DUO/16/0043(1)**

Date of preparation: May 2017
COPD: risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds.¹

Prescribing Information

Presentation: DuoResp® Spiromax® 160µg/4.5µg: Each delivered dose contains 160µg of budesonide and 4.5µg of formoterol fumarate dihydrate. Maintenance therapy 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 daily. Young children under 4 years old: 1-2 inhalations twice daily. Patients with thyrotoxicosis, diabetics, elderly patients, children < 18 years of age.

DuoResp® Spiromax® 320µg/9µg: Each delivered dose contains 320µg of budesonide and 9µg of formoterol fumarate dihydrate.

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 is 2 inhalations per day, given either as one inhalation morning and evening or as 2 inhalations in the 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 8 inhalations per day 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).

DuoResp® Spiromax® 320µg/9µg and Symbicort® Turbohaler® 200/6µg (120 doses) and Symbicort® Turbohaler® 400/12µg (60 doses)

£29.97

£38.00

References


