

Product current status:

Product proposed status:

Date of next meeting:

Decision: Yes  No

Restricted use:

### Drug name

**Fostair® (beclometasone/formoterol pressurised metered dose inhaler)**

### Indication

- Fostair is indicated in the regular treatment of asthma in adults where use of a combination product (ICS and LABA) is appropriate for:<sup>1</sup>
  - patients not adequately controlled with ICS and 'as needed' inhaled short-acting beta<sub>2</sub>-agonist **or**
  - patients already adequately controlled on both ICS and LABA.

NB Fostair is not appropriate for treatment of acute asthma attacks.

### Dosage

- One or two inhalations to be taken twice daily.<sup>1</sup>

### NICE recommendations

- For adults with chronic asthma in whom treatment with an ICS and LABA is considered appropriate, the following apply:<sup>2</sup>
  - The use of a combination device within its marketing authorisation is recommended as an option
  - If a combination device is chosen then the least costly device that is suitable for the individual is recommended.

### BTS/SIGN recommendations

#### Step 3: initial add-on therapy

- Add-on therapy is indicated when there is inadequate control on low-dose ICS<sup>3</sup>
- First choice of add-on therapy is the addition of an inhaled LABA, which improves lung function and symptoms, and decreases exacerbations<sup>3</sup>
- Many patients will benefit more from add-on therapy than from increasing ICS above 200 µg BDP/day<sup>3</sup>

- Combination inhalers have the advantage of guaranteeing that the LABA is not taken without ICS.<sup>3</sup>

### Evidence for use

- Fostair:
  - reduces use of rescue medication and improves asthma symptoms in patients previously uncontrolled at Step 2 of the BTS/SIGN guideline<sup>4-7</sup>
  - is the first fixed-combination inhaler to demonstrate a statistical superiority in asthma control versus its separate components<sup>8</sup>
  - is less expensive than comparable doses of Symbicort® or Seretide™<sup>9</sup>
- Fostair 100/6 (two puffs bd) has been shown to be comparable to Symbicort® 200/6 (two puffs bd) and Seretide™ 125 Evohaler™ (two puffs bd)<sup>4,5,9</sup>
- Fostair contains quick-acting formoterol, which triggers the bronchodilatory effect within 1–3 minutes<sup>1</sup>
- Fostair is the only combination inhaler that delivers extrafine particles allowing a reduced beclometasone dose to be used:<sup>1,9</sup>
  - 100 µg BDP extrafine in Fostair is equivalent to 250 µg BDP in a non-extrafine formulation.

### Contraindications and precautions

Fostair:<sup>1</sup>

- is contraindicated in patients with a known hypersensitivity to the active substances or any of the excipients
- should be used with caution in patients with cardiovascular disorders including arrhythmias and QTc prolongation, thyrotoxicosis, diabetes, phaeochromocytoma, untreated hypokalaemia, tuberculosis, and fungal and viral infections (see prescribing information).

### Common side-effects

- Common side-effects include pharyngitis, headache, and dysphonia (see prescribing information for full details).<sup>1</sup>

### Budgetary implications

- Volume and costs of combination inhalers are increasing year on year and are one of the highest classes of spend<sup>10,11</sup>

ICS=inhaled corticosteroid; LABA=long-acting beta<sub>2</sub>-agonist; BDP=beclometasone dipropionate

- NICE guidance states that 'if a combination device is chosen then the least costly device that is suitable for the individual is recommended'<sup>2</sup>
- Fostair has the lowest acquisition cost of dose-comparable combination inhalers<sup>9</sup>
- It is estimated that:<sup>12</sup>
  - 75% of asthma admissions are preventable
  - patients who do not have a written asthma action/management plan are four times more likely to require hospital treatment.

## Key points

### Fostair:

- reduces use of rescue medication and improves asthma symptoms in patients previously uncontrolled at Step 2 of the BTS/SIGN guideline<sup>4-7</sup>
- is the first fixed-combination inhaler to demonstrate a statistical superiority in asthma control versus its separate components.<sup>8</sup>

### Fostair® (beclometasone dipropionate and formoterol fumarate dihydrate pressurised inhalation solution)

Please refer to Summary of Product Characteristics (SmPC) before prescribing

#### Prescribing information

**Presentations:** Pressurised inhalation solution containing 100 micrograms of beclometasone dipropionate and 6 micrograms of formoterol fumarate dihydrate per actuation. **Indications:** Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta<sub>2</sub>-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta<sub>2</sub>-agonist; or patients already adequately controlled on both inhaled corticosteroids and long-acting beta<sub>2</sub>-agonists. Not appropriate for treatment of acute asthma attacks. **Dosage and Administration:** For inhalation use only. Fostair is not intended for the initial management of asthma. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of beta<sub>2</sub>-agonists and/or corticosteroids by individual inhalers should be prescribed. Beclometasone dipropionate in Fostair is characterised by an extrafine particle size distribution which results in a more potent effect than formulations of beclometasone dipropionate with a non-extrafine particle size distribution (100 micrograms of beclometasone dipropionate extrafine in Fostair are equivalent to 250 micrograms of beclometasone dipropionate in a non-extrafine formulation). Therefore the total daily dose of beclometasone dipropionate administered in Fostair should be lower than the total daily dose of beclometasone dipropionate administered in a non-extrafine beclometasone dipropionate formulation. **Adults 18 years and above:** one or two inhalations twice daily, maximum four inhalations daily. **Children and adolescents under 18 years:** The safety and efficacy of Fostair has not yet been established. No data are available with Fostair in children under 12 years of age. Only limited data are available in adolescents between 12 and 17 years of age. Therefore Fostair is not recommended for children and adolescents under 18 years until further data become available. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. Fostair may be used with the AeroChamber Plus™ spacer device. Patients should be advised in the proper use and care of their inhaler and spacer. **Contraindications:** Hypersensitivity to any of the components. **Warnings and Precautions:** Cardiovascular disorders including cardiac arrhythmias and QTc prolongation, thyrotoxicosis, diabetes mellitus, phaeochromocytoma, untreated hypokalaemia, active or quiescent pulmonary tuberculosis, fungal and viral infections. Fostair should not be used as the first treatment for asthma, should not be initiated during an exacerbation, or during significantly worsening or acutely deteriorating asthma, and should not be stopped abruptly. If patients find the treatment ineffective medical attention must be sought. Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing, treat immediately. Patients should take Fostair as prescribed even when asymptomatic. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for long periods. These effects are much less likely to occur with inhaled than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract, glaucoma and more rarely a range of psychological or

## References

1. Chiesi Limited. *Fostair 100/6 micrograms per actuation pressurised inhalation solution. Summary of product characteristics.* October 2011.
2. National Institute for Health and Clinical Excellence. *Inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over.* Technology Appraisal 138. London: NICE, 2008.
3. British Thoracic Society, Scottish Intercollegiate Guidelines Network. *British guideline on the management of asthma.* SIGN 101. Edinburgh: SIGN, 2011.
4. Papi A, Paggiaro P, Nicolini G et al. ICAT SE study group. Beclomethasone/formoterol vs. fluticasone/salmeterol inhaled combination in moderate to severe asthma. *Allergy* 2007; **62** (10): 1182–1188.
5. Papi A, Paggiaro P, Nicolini G et al. Beclomethasone/formoterol versus budesonide/formoterol combination therapy in asthma. *Eur Respir J* 2007; **29** (4): 682–689.
6. Huchon G, Magnusson H, Chuchalin A et al. Lung function and asthma control with beclometasone and formoterol in a single inhaler. *Respir Med* 2009; **103**: 41–49.
7. Rigamonti E, Kottakis I, Pelc M et al. *Comparison of a new extrafine beclometasone dipropionate HFA 134a-formulated pMDI with a standard BDP CFC pMDI in adults with moderate persistent asthma (P1236).* Poster session presented at Annual Congress of European Respiratory Society: September 2–6, 2006; Munich, Germany.
8. Barnes P, Nicolini G, Bizzi A, Singh D. *Do ICS/LABA fixed combination inhalers provide superior asthma control compared to separate inhalers?* (2036). Abstract presented at Annual Congress of European Respiratory Society: September 18–22, 2010; Barcelona, Spain.
9. Monthly Index of Medical Specialities. *MIMS December 2011.*
10. NHS Business Services Authority. *Prescribing analysis charts—respiratory.* October 2010 (accessed 18 May 2011).
11. NHS Information Centre. *Prescription cost analysis England 2010.* Available at: [www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-england-2010](http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-england-2010) (accessed 18 May 2011).
12. Asthma UK website. *Key facts and statistics.* [www.asthma.org.uk/news\\_media/media\\_resources/for\\_journalists\\_key.html](http://www.asthma.org.uk/news_media/media_resources/for_journalists_key.html) (accessed 12 January 2012).

behavioural effects (particularly in children). Titrate to the lowest dose at which effective control of asthma is maintained to minimise systemic effects. Special care is needed in transferring patients from oral steroids. Fostair contains a small amount of ethanol (approximately 7mg per actuation); at normal doses the amount of ethanol is negligible and does not pose a risk to patients. Patients should rinse mouth after inhalation to minimise risk of oropharyngeal candida infection. **Interactions:** Beclometasone dipropionate undergoes a very rapid metabolism via esterase enzymes without involvement of the cytochrome p450 system. Avoid beta-blockers (including eye drops). Caution is required when theophylline or other beta-adrenergic drugs are prescribed concomitantly with formoterol. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines, MAOIs and 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 administration with MAOIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertensive reactions. Risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Theoretical potential for interaction in sensitive patients taking disulfiram or metronidazole. **Pregnancy and Lactation:** No relevant clinical data. Should only be used during pregnancy or lactation if the expected benefits outweigh the potential risks. **Undesirable effects:** *Common:* pharyngitis, headache, dysphonia. *Uncommon:* influenza, oral fungal infection, oropharyngeal and oesophageal candidiasis, vulvovaginal candidiasis, gastroenteritis, sinusitis, rhinitis, granulocytopenia, dermatitis allergic, hypokalaemia, hyperglycaemia, restlessness, tremor, dizziness, otosclerotic cardiac arrhythmias, hyperaemia, flushing, cough, productive cough, throat irritation, asthmatic crisis, diarrhoea, dry mouth, dyspepsia, dysphagia, burning sensation of the lips, nausea, dysgeusia, pruritus, rash, hyperhidrosis, muscle spasms, myalgia, C-reactive protein increased, platelet count increased, free fatty acids increased, blood insulin increased, blood ketone body increased. *Rare:* ventricular extrasystoles, angina pectoris, bronchospasm paradoxical, urticaria, angioedema, nephritis, blood pressure increased, blood pressure decreased. *Very rare:* thrombocytopenia, hypersensitivity reactions, adrenal suppression, glaucoma, cataract, atrial fibrillation, dyspnoea, exacerbation of asthma, growth retardation in children and adolescents, oedema peripheral, bone density decreased. *Unknown:* psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children). **Legal Category:** POM Packs and Prices: Fostair 100/6 (PL08829/0156) £29.32. Each inhaler contains 120 actuations. TM denotes Trademark. AeroChamber Plus™ is a trademark of Trudell Medical International. **Full prescribing information is available from the Marketing Authorisation Holder:** Chiesi Limited, Cheadle Royal Business Park, Highfield, Cheadle, SK8 3GY. **Date of preparation:** October 2011.

### Adverse events should be reported.

Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Adverse events should also be reported to Chiesi Limited. (address as above)  
Tel: 0161 488 5555