HAUTE AUTORITÉ DE SANTÉ

PULMONOLOGY
New medicinal product
December 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

AIRFLUSAL FORSPIRO (fluticasone/salmeterol), corticosteroid/β2 agonist

No clinical benefit demonstrated in asthma and COPD by comparison with SERETIDE DISKUS 500 µg/50 µg/dose.

Main points

◗ AIRFLUSAL FORSPIRO has Marketing Authorisation in:
- Maintenance treatment of asthma in situations where the administration by inhalation of a product combining a corticosteroid and a long-acting β2 agonist bronchodilator is justified:
in patients who are inadequately controlled by inhaled corticosteroid therapy and "as-needed" dosing with an inhaled short-acting β2 agonist bronchodilator or
in patients controlled by inhaled corticosteroid therapy in combination with maintenance treatment with a long-acting inhaled β2 agonist.
- Symptomatic treatment of chronic obstructive pulmonary disease (COPD) in patients with an FEV1 (measured prior to administration of a bronchodilator) < 60% of the theoretical value and who have a history of repeated exacerbations and significant symptoms despite maintenance bronchodilator treatment.

◗ No clinical benefit has been demonstrated by comparison with SERETIDE DISKUS 500 µg/50 µg/dose.

Therapeutic use

- **In severe asthma**, maintenance treatment most often necessitates a combination of high-dose inhaled corticosteroids, bronchodilators with a prolonged duration of action (long-acting β2 agonist, prolonged-release theophylline, or even an anticholinergic) and oral corticosteroid therapy. A distinction must be made here between short courses of oral corticosteroids (6 to 8 days) and continuous oral corticosteroid therapy, which should be pursued only if the doctor makes regular attempts to reduce the dosage or stop it altogether. The aim of the combination of high-dose inhaled corticosteroids and long-acting bronchodilators is to minimise or reduce the frequency of dosing in maintenance therapy with oral corticosteroids.

- **In COPD** patients who are not inconvenienced by dyspnoea (mild COPD, stage I) on an everyday basis, "as needed" use of an inhaled short-acting bronchodilator is usually sufficient.
Patients with stage II (moderate) to stage IV (very severe) COPD whose dyspnoea interferes with activities of daily life should be offered maintenance treatment with an inhaled long-acting bronchodilator. Three long-acting β2 agonists (formoterol, salmeterol, indacaterol) and two long-acting anticholinergics (tiotropium, glycopyrronium) have Marketing Authorisation in the symptomatic maintenance treatment of COPD. Their efficacy is the same.
In patients with an FEV1 < 50% of the theoretical value who experience repeated severe (stage III) or very severe (stage IV) exacerbations, inhaled corticosteroids are recommended only if used alongside an inhaled long-acting bronchodilator. In France, only inhaled corticosteroids in a fixed-dose combination with a long-acting β2 agonist have Marketing Authorisation in this indication.

- **Role of the medicinal product in the therapeutic strategy**
AIRFLUSAL FORSPIRO is a second-line treatment in asthma and in severe COPD (FEV1 < 60% of the theoretical value) in patients with a history of repeated exacerbations and significant symptoms despite regular treatment with a long-acting bronchodilator.

Clinical data

- Bioequivalence in healthy subjects, in terms of total systemic exposure, has been demonstrated between each of the active substances contained in the two fluticasone propionate/salmeterol 500 µg/50 µg combinations (administered using the Forspiro or Diskus device). The therapeutic equivalence between AIRFLUSAL FORSPIRO 500 µg/50 µg/dose and SERETIDE DISKUS 500 µg/50 µg/dose has been validated by this demonstration of bioequivalence.
- The non-inferiority of AIRFLUSAL FORSPIRO 500 µg/50 µg/dose versus SERETIDE DISKUS 500 µg/50 µg/dose has been demonstrated in patients with moderate to severe persistent asthma.
- Safety data from clinical studies have not brought to light any new safety signals, special risks or unexpected adverse events.

Benefit of the medicinal product

- The actual benefit* of AIRFLUSAL FORSPIRO is
  - substantial in the indication “asthma”,
  - moderate in the indication “chronic obstructive pulmonary disease”.
- AIRFLUSAL FORSPIRO does not provide clinical added value** (CAV V) compared with SERETIDE DISKUS inhalation powder 500 µg/50 µg/dose.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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[i] * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".