

Alvesco[®] Inhaler Technique



STEP 1. Remove the inhaler mouth piece cover



STEP 2. Check that all pieces are clean and dry



STEP 3. Hold the inhaler upright with your forefinger on the top and thumb on the bottom of it



STEP 4. Breathe out as far as is comfortable



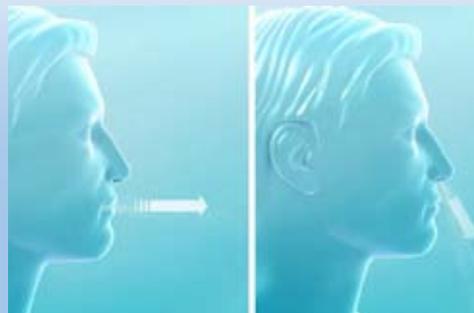
STEP 5. Place the mouth piece in your mouth and close your lips firmly around it



STEP 6. Begin breathing in through your mouth, press down on top of the inhaler to release a puff and continue to breathe in



STEP 7. Remove the inhaler from your mouth and continue holding your breath for approximately 10 seconds



STEP 8. Breathe out slowly. If you need to take more than one puff, repeat steps 3-7.

inhaler technique



CartAlvesco 80 and 160 micrograms pressurised inhalation, solution

ABBREVIATED PRESCRIBING INFORMATION. For more information, please, refer to Summary of Product Characteristics (SPC) of last revision 18 May 2011.

Presentation: Alvesco 80 and 160 micrograms pressurised inhalation, solution

Each actuation (delivered dose from the mouthpiece) delivers a pressurised inhalation solution containing either 160 micrograms or 80 micrograms of the active ingredient ciclesonide. The inhalation solution also contains norflurane (HFA-134a) and ethanol, anhydrous. **Therapeutic indications:** Treatment to control persistent asthma in adults and adolescents (12 years and older). **Posology and method of administration:** The medicinal product is for inhalation use only. The recommended dose of Alvesco is 160 micrograms once daily, which leads to asthma control in the majority of patients. However in severe asthmatics, a 12 week study has shown that a dose of 640 micrograms/day (given 320 micrograms twice daily) has demonstrated a reduction in the frequency of exacerbations but without an improvement in lung function (for more information, see full SPC section 5.1). Dose reduction to 80 micrograms once daily may be an effective maintenance dose for some patients. Alvesco should preferably be administered in the evening although morning dosing of Alvesco has also been shown to be effective. The final decision on evening or morning dosing should be left to the discretion of the physician. Symptoms start to improve with Alvesco within 24 hours of treatment. Once control is achieved, the dose of Alvesco should be individualised and titrated to the minimum dose needed to maintain good asthma control. **Contraindications:** Hypersensitivity to ciclesonide or any of the excipients. **Special warnings and precautions for use:** As with all inhaled corticosteroids, Alvesco should be administered with caution in patients with active or quiescent pulmonary tuberculosis, fungal, viral or bacterial infections, and only if these patients are adequately treated. As with all inhaled corticosteroids, Alvesco is not indicated in the treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Alvesco is not designed to relieve acute asthma symptoms for which an inhaled short-acting bronchodilator is required. Patients should be advised to have such rescue medication available. **Systemic Effects:** Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Patients with severe hepatic impairment should be monitored for potential systemic effects. **Interactions:** Concomitant administration of potent inhibitors of CYP 3A4 (e.g. ketoconazole, itraconazole and ritonavir or nelfinavir) should be avoided unless the benefit outweighs the increased risk of systemic side effects of corticosteroids. **Undesirable effects:** Approximately 5% of patients experienced adverse reactions in clinical trials with Alvesco given in the dose range 40 to 1280 micrograms per day. In the majority of cases, these were mild and did not require discontinuation of treatment with Alvesco. **Uncommon effects:** nausea, vomiting, bad taste, application site reactions, application site dryness, oral fungal infections, headache, dysphonia, cough after inhalation, paradoxical bronchospasm, eczema and rash. **Rare effects:** palpitations, abdominal pain, dyspepsia, angioedema, hypersensitivity, hypertension. Other effects (unknown frequency): psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children). Paradoxical bronchospasm may occur immediately after dosing and is an unspecific acute reaction to all inhaled medicinal products. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. **Effects on ability to drive and use machines:** Inhaled ciclesonide has no or negligible influence on the ability to drive and use machines. **Pregnancy and lactation:** As with other inhaled glucocorticoids, ciclesonide should only be used during pregnancy or lactation if the potential benefit to the mother justifies the potential risk to the mother, fetus or child. The lowest effective dose of ciclesonide needed to maintain adequate asthma control should be used. **Marketing authorisation holder:** Nycomed GmbH, Byk-Gulden-Str. 2, D-78467 Konstanz, Germany. **Price and packages:** For more information about prices and packages please contact the local Nycomed organization in your country. **Legal Category:** Prescription Only Medicine.

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