

Important Information: New asthma maintenance treatment available!

Dear Pharmacist:

AstraZeneca is pleased to announce the availability of PULMICORT FLEXHALER™ — the budesonide safety profile you trust in a new device.

As the asthma treatment market continues to evolve, so does the AstraZeneca commitment to health care professionals and patients. This dedication is supported by the introduction of PULMICORT FLEXHALER™. With the addition of this new inhaled corticosteroid therapy to the AstraZeneca respiratory portfolio, PULMICORT TURBUHALER® (budesonide inhalation powder) will be phased out.



Budesonide safety profile includes	Designed with your asthma patients in mind
<ul style="list-style-type: none">• Budesonide was evaluated in the CAMP study, a long-term, controlled US study of treatments for childhood asthma¹• The ONLY Pregnancy Category B inhaled corticosteroid for the treatment of asthma• Budesonide inhalation powder has been FDA approved for almost a decade for the treatment of asthma*• Please see Important Information below	<ul style="list-style-type: none">• Two prescribing strengths for adjustable dosing— 180 mcg and 90 mcg• Numeric dose counter helps patients track their therapy• Tapered mouthpiece provides a contoured fit for children and adults alike

Important Information

PULMICORT FLEXHALER™ is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age or older. PULMICORT FLEXHALER™ is not a bronchodilator and is NOT indicated for the relief of acute bronchospasm. Common adverse events reported in clinical trials, regardless of relationship to treatment, include nasopharyngitis, nasal congestion, pharyngitis, allergic rhinitis, and viral upper respiratory tract infection. In the CAMP (Childhood Asthma Management Program) study, the primary efficacy endpoint was not met. Controlled clinical studies have shown that orally inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. The growth of pediatric patients receiving orally inhaled corticosteroids, including PULMICORT FLEXHALER™, should be monitored routinely. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks and benefits associated with alternative therapies. To minimize the systemic effects of inhaled corticosteroids, including PULMICORT FLEXHALER™, each patient should be titrated to his/her lowest effective dose. Because studies in humans cannot rule out the possibility of fetal harm, PULMICORT FLEXHALER™ should be used in pregnancy only if clearly needed.

A definitive comparative therapeutic ratio between PULMICORT FLEXHALER™ and PULMICORT TURBUHALER has not been established. For patients who have been on PULMICORT TURBUHALER the dose of PULMICORT FLEXHALER™ may not be predicted by the dose of that product. The clinical response of PULMICORT FLEXHALER™ compared with PULMICORT TURBUHALER tends to be lower (see Clinical Studies in the accompanying full Prescribing Information). Any patient who is switched from PULMICORT TURBUHALER to PULMICORT FLEXHALER™ should be dosed appropriately, taking into account the dosing recommendations, and titrating the dose as dictated by the clinical response.

Additional News

Please contact your wholesaler today to place your order for PULMICORT FLEXHALER™. If you have additional questions, please call 1-800-236-9933 or visit our web site at PULMICORTFLEXHALER.COM.

Sincerely,

Kathy L. Lampl, MD
Associate Director, Clinical Development
Medical Sciences, Respiratory

Please see Indications and Important Safety Information on reverse side and accompanying full Prescribing Information for PULMICORT FLEXHALER™ and PULMICORT TURBUHALER.

*Approved by the FDA as PULMICORT TURBUHALER® in June 1997.

Pulmicort 90
&
Flexhaler 180 mcg
(budesonide inhalation powder,
90 mcg & 180 mcg)

Indications and Important Safety Information for PULMICORT FLEXHALER™ (budesonide inhalation powder, 90 mcg & 180 mcg)

- PULMICORT FLEXHALER™ is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age or older
- PULMICORT FLEXHALER™ is not a bronchodilator and is NOT indicated for the relief of acute bronchospasm
- Particular care is needed for patients who are transferred from systemically active corticosteroids to PULMICORT FLEXHALER™ because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids (see WARNINGS in full Prescribing Information)
- Patients taking immunosuppressant doses of corticosteroids should avoid exposure to infections such as chicken pox and measles
- It is possible that systemic corticosteroid effects such as hypercorticism, reduced bone mineral density, and adrenal suppression may appear in a small number of patients, particularly at higher doses
- Inhaled corticosteroids may cause a reduction in growth velocity. The long-term effect on final adult height is unknown
- Rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the inhaled administration of corticosteroids
- Common adverse events reported in clinical trials, regardless of relationship to treatment, include nasopharyngitis, nasal congestion, pharyngitis, allergic rhinitis, and viral upper respiratory tract infection

Indications and Important Safety Information for PULMICORT TURBUHALER® (budesonide inhalation powder)

- PULMICORT TURBUHALER is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age or older
- PULMICORT TURBUHALER is not a bronchodilator and is NOT indicated for the relief of acute bronchospasm
- Particular care is needed for patients who are transferred from systemically active corticosteroids to PULMICORT TURBUHALER because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids (see WARNINGS in full Prescribing Information)
- Patients taking immunosuppressant doses of corticosteroids should avoid exposure to infections such as chicken pox and measles
- It is possible that systemic corticosteroid effects such as hypercorticism, reduced bone mineral density, and adrenal suppression may appear in a small number of patients, particularly at higher doses
- Inhaled corticosteroids may cause a reduction in growth velocity. The long-term effect on final adult height is unknown
- Rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the inhaled administration of corticosteroids
- Common adverse events reported in clinical trials, regardless of relationship to treatment, include respiratory infection, headache, oral candidiasis, pharyngitis, voice alteration, and sinusitis

Please see accompanying full Prescribing Information for PULMICORT FLEXHALER™ and PULMICORT TURBUHALER.

Reference: 1. Childhood Asthma Management Program Research Group. Long-term effects of budesonide or nedocromil in children with asthma. *N Engl J Med.* 2000;343:1054-1063.



PULMICORT FLEXHALER is a trademark and PULMICORT TURBUHALER is a registered trademark of the AstraZeneca group of companies.

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