

Dear Pharmacist:

To help control pediatric asthma, the maker of PULMICORT RESPULES introduces a **new once-daily 1-mg ampule** to help meet individual patient dosing needs.

The new 1-mg ampule joins the existing 0.25-mg and 0.5-mg ampules, all of which come in a 2-mL suspension. The addition of the 1-mg ampule provides health care professionals with a greater range of dosing options to help pediatric patients, 12 months to 8 years of age, achieve and maintain asthma control.



Proven efficacy and safety demonstrated in three pivotal 3-month clinical trials with over 900 patients*...now in a new 1-mg ampule

- ✓ Significant reduction in **daytime and nighttime asthma symptoms**^{1,2}
- ✓ Significant reduction in **rescue β_2 -agonist use**^{3,4}
- ✓ Improvement in **lung function**^{†5}
- ✓ A well-established **safety profile**

Due to the higher concentration, the contents of the 1-mg/2-mL ampule of PULMICORT RESPULES appear more white and translucent (cloudy), compared to the 0.25-mg/2-mL and 0.5-mg/2-mL ampules. As stated in the Patient Instructions for Use, the ampule should be gently shaken in a circular motion to resuspend the product prior to use.

PULMICORT RESPULES is indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.

PULMICORT RESPULES 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, included respiratory infection, rhinitis, coughing, otitis media, viral infection, gastroenteritis, ear infection, oral thrush/candidiasis, and epistaxis.

Please see Important Safety Information on reverse side and accompanying full Prescribing Information.

The new once-daily 1-mg ampule is available now from your wholesaler. Please be advised that you will see prescriptions soon.

For additional information or to ask questions, please contact the Information Center at AstraZeneca at 1-800-236-9933, Monday through Friday, from 8 AM to 7 PM ET, excluding holidays. Or visit us at www.pulmicortrespules.com.

Sincerely,

A handwritten signature in black ink that reads 'Kathy L. Lampl MD'.

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



* Data based on children 12 months to 8 years of age.

† Lung function is defined as peak expiratory flow measurement in children able to perform pulmonary function tests.

Pulmicort
RESPULES
(budesonide inhalation suspension)

A graphic of a white ampule with a blue cap. The text '0.25 mg', '0.5 mg', and '1 mg' is written on the ampule.

Important Safety Information

- Inhaled corticosteroids may cause a reduction in growth velocity. The long-term effect on final adult height is unknown
- PULMICORT RESPULES, like other inhaled corticosteroids, may impact the hypothalamic-pituitary-adrenal axis, especially in susceptible individuals, in younger children, and in patients given high doses for prolonged periods
- Particular care is needed for patients who are transferred from systemically active corticosteroids to less systemically available inhaled corticosteroids, because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids (see WARNINGS in full Prescribing Information)
- Patients taking immunosuppressant doses of corticosteroids should avoid exposure to infections such as chicken pox and measles

Please see additional safety information on the reverse side and accompanying full Prescribing Information.



References: **1.** Kemp JP, Skoner DP, Szeffler SJ, et al. Once-daily budesonide inhalation suspension for the treatment of persistent asthma in infants and young children. *Ann Allergy Asthma Immunol.* 1999;83:231-239. **2.** Data on file, DA-RES-04. **3.** Shapiro G, Mendelson L, Kraemer MJ, et al. Efficacy and safety of budesonide inhalation suspension (Pulmicort Respules) in young children with inhaled steroid-dependent, persistent asthma. *J Allergy Clin Immunol.* 1998;102:789-796. **4.** Data on file, DA-RES-09. **5.** Baker JW, Mellon M, Wald J, et al. A multiple-dosing, placebo-controlled study of budesonide inhalation suspension given once or twice daily for treatment of persistent asthma in young children and infants. *Pediatrics.* 1999;103:414-421.

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Pulmicort
RESPULES
(budesonide inhalation suspension)

A small graphic of a white ampule with a blue cap. Inside the ampule, the dosages "0.25 mg", "0.5 mg", and "1 mg" are listed vertically in blue.