

(<https://www.aphadruginfoline.com>)

[Home](#) > Once-daily inhaled corticosteroid approved to treat asthma in children aged 5 to 11 years

Generic Name:

Fluticasone furoate

Trade Name:

Arnuity Ellipta

Company:

GlaxoSmithKline

Notes:

GlaxoSmithKline [announced](#) FDA approval of fluticasone furoate, a once-daily inhaled corticosteroid, for maintenance treatment of asthma in children aged 5 to 11 years.

The drug is delivered as a 50-mcg, once-daily dose using the Ellipta inhaler. It is not indicated for relief of acute bronchospasm.

The product was approved in August 2014 for maintenance treatment of asthma in patients aged 12 years and older.

Approval was based on data from a pivotal study assessing the efficacy and safety of once-daily fluticasone furoate, compared with placebo, in 593 children aged 5 to 11 years (inclusive) with asthma. Inhaled fluticasone propionate 100 mcg twice daily was included as an active control.

Results showed statistically significant improvements with once-daily fluticasone furoate 50 mg compared with placebo (19.5 L/min; $P < .001$).

The most common adverse reactions, reported in 3% or more of pediatric subjects aged 5 to 11 years, are pharyngitis, bronchitis, and viral infection.

Medication Monitor Categories:

[Supplemental Approvals](#)

Source URL: <https://www.aphadruginfoline.com/supplemental-approvals/once-daily-inhaled-corticosteroid-approved-treat-asthma-children-aged-5-11>