



Arnuity[®] Ellipta[®] (fluticasone furoate) – Expanded indication

- On May 21, 2018, [GlaxoSmithKline](#) announced the [FDA approval](#) of [Arnuity Ellipta \(fluticasone furoate\)](#) for the maintenance treatment of asthma as prophylactic therapy in patients aged 5 years and older.
 - Previously, Arnuity Ellipta was only approved for use in patients ≥ 12 years of age.
 - Arnuity Ellipta is not indicated for relief of acute bronchospasms.
- The safety and efficacy of Arnuity Ellipta in patients 5 to 11 years of age with asthma were demonstrated in a 12-week clinical study. Patients were randomized to Arnuity Ellipta (25 mcg, 50 mcg, or 100 mcg) or placebo. Inhaled fluticasone propionate 100 mcg twice daily was included as an active control.
 - Results showed improvements in the mean change from baseline in daily morning peak expiratory flow (PEF) with all doses of Arnuity Ellipta vs. placebo.
 - Given the demonstration of efficacy of Arnuity Ellipta 100 mcg and 200 mcg in the adult and adolescent population, the results support the efficacy of Arnuity Ellipta 50 mcg once daily in pediatric patients aged 5 to 11 years.
 - Comparable differences in PEF from placebo were also achieved with inhaled fluticasone propionate.
- The most common adverse reactions ($\geq 3\%$) reported with Arnuity Ellipta use in patients aged 5 to 11 years were pharyngitis, bronchitis, and viral infection.
- The recommended dose of Arnuity Ellipta in patients aged 5 to 11 years is one inhalation of Arnuity Ellipta 50 mcg once daily.
 - The usual recommended starting dose for patients ≥ 12 years of age not on an inhaled corticosteroid is 100 mcg once daily.
 - For others, the starting dose should be based on previous asthma drug therapy and disease severity.
 - For patients ≥ 12 years of age who do not respond to the 100 mcg dose after two weeks of therapy, replacement with Arnuity Ellipta 200 mcg may provide additional asthma control.
- To support the expanded indication, Arnuity Ellipta will be available as a new 50 mcg/actuation formulation.



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