

Fasenra® (benralizumab) – Expanded indication

- On April 5, 2024, the <u>FDA approved</u> AstraZeneca's <u>Fasenra (benralizumab)</u>, as add-on maintenance treatment of patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.
 - Fasenra was previously approved for this indication in patients aged 12 years and older.
- In addition to the expanded indication, the FDA approved a new Fasenra 10 mg/0.5 mL singledose prefilled syringe formulation.
 - Fasenra was previously available as a 30 mg/mL single-dose prefilled syringe and a single-dose autoinjector pen.
- The approval of Fasenra for the expanded indication was supported by evidence from adequate and well-controlled trials in adults and adolescents with additional pharmacokinetic, pharmacodynamic, and safety data in pediatric patients aged 6 to 11 years.
 - The effectiveness of Fasenra in pediatric patients 6 to 11 years of age is extrapolated from efficacy in three clinical trials (SIROCCO, CALIMA, and ZONDA) with support from pharmacokinetic analysis and pharmacodynamic response in pediatric patients aged 6 to 11 years compared to adults and adolescents.
- The recommended dose of Fasenra for pediatric patients 6 to 11 years of age is based on body weight:
 - Less than 35 kg: 10 mg (one injection) administered subcutaneously (SC) every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
 - 35 kg or more: 30 mg (one injection) administered SC every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
- Refer to the Fasenra drug label for dosing in patients 12 years of age and older.



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