



### FluLaval<sup>®</sup> Quadrivalent (influenza vaccine) – Expanded Indication

- On November 18, 2016, [GlaxoSmithKline announced](#) the FDA approval of [FluLaval Quadrivalent \(influenza vaccine\)](#) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluLaval Quadrivalent is approved for use in persons  $\geq 6$  months of age.
  - Previously, FluLaval Quadrivalent was approved for use in patients  $\geq 3$  years of age.
- [Fluzone<sup>®</sup> Quadrivalent \(influenza vaccine\)](#) is another currently available quadrivalent influenza vaccine approved for use in persons  $\geq 6$  months of age.
- The efficacy of FluLaval Quadrivalent in children aged 6 through 35 months was demonstrated in a clinical study of 2,424 patients randomized to receive FluLaval Quadrivalent or Fluzone Quadrivalent. FluLaval Quadrivalent demonstrated non-inferiority to Fluzone Quadrivalent for all vaccine strains based on adjusted geometric mean antibody titers and seroconversion rates.
- In children aged 6 through 35 months, the most common ( $\geq 10\%$ ) solicited local adverse reaction was pain. The most common solicited systemic adverse events were irritability, drowsiness, and loss of appetite.
- The recommended dose for persons  $\geq 6$  months of age of FluLaval is one or two doses (0.5 mL each) depending on vaccination history per the annual [Advisory Committee on Immunization Practices](#) recommendation on the prevention and control of influenza with vaccines.
  - If two doses are needed, each dose should be administered at least 4 weeks apart.



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