



## Diovan® (valsartan) – Expanded indication

- On April 19, 2021, the [FDA approved](#) Novartis' [Diovan \(valsartan\)](#), for the treatment of hypertension, to lower blood pressure in adults and pediatric patients one year of age and older.
  - Diovan was previously approved for this indication in patients 6 years of age and older.
- Diovan is also approved:
  - To reduce the risk of hospitalization for heart failure in adult patients with heart failure.
  - In clinically stable adult patients with left ventricular failure or left ventricular dysfunction following myocardial infarction, to reduce the risk of cardiovascular mortality.
- Diovan is available [generically](#).
- The approval of Diovan for the expanded indication was based on three randomized, double-blind clinical studies in 290 children aged between 1 to less than 6 years of age. The adverse experience profile of Diovan was similar to that described for adults.
- Diovan carries a boxed warning for fetal toxicity.
- The recommended starting dosage of Diovan for the treatment of pediatric hypertension 1 to 16 years of age is 1 mg/kg once daily (up to 40 mg total). A higher starting dose of 2 mg/kg may be considered in selected cases when a greater reduction of blood pressure is needed. The dosage should be adjusted according to blood pressure response and tolerability, up to a maximum dose of 4 mg/kg once daily (maximum daily dose 160 mg).
  - Refer to the Diovan drug label for dosing in adults and for its other indications.



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