



### Zipsor® (diclofenac potassium) – Expanded indication

- On May 25, 2021, the [FDA approved](#) Assertio Therapeutics' [Zipsor \(diclofenac potassium\)](#) capsule for relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.
  - Previously, Zipsor was indicated only for adult patients for the relief of mild to moderate acute pain.
- The safety and effectiveness of Zipsor in pediatric patients 12 years to 17 years of age have been established. Use of Zipsor in this age group is based on extrapolation of efficacy from adequate and well-controlled studies in adults and supported by pharmacokinetic and safety data from two open-label studies in 49 patients 12 years to 17 years of age with mild to moderate acute pain and one active-controlled study in 76 pediatric patients 12 years to 16 years of age with orthodontic discomfort.
  - Based on the available data, the plasma diclofenac concentration in adolescent patients was comparable to that observed in healthy adults.
  - The safety profile of Zipsor in adolescent patients was similar to adults.
- Zipsor carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- The recommended dose of Zipsor for the treatment of adult and pediatric patients 12 years of age and older is 25 mg orally four times a day.
- Different dose strengths and formulations of oral diclofenac are not interchangeable. This difference should be taken into consideration when changing strengths or formulations. The only approved dosing regimen for Zipsor is 25 mg four times a day.



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