

## Vimovo<sup>®</sup> (esomeprazole magnesium/naproxen) – New and expanded indications

- On July 6, 2017, the FDA approved Horizon Pharmaceuticals' [Vimovo \(esomeprazole magnesium/naproxen\)](#) delayed-release tablets, in adults and adolescent patients ≥ 12 years of age weighing ≥ 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers; and the naproxen component of Vimovo is indicated for relief of signs and symptoms of juvenile idiopathic arthritis (JIA) in adolescent patients.
  - Previously, Vimovo was only approved in adult patients for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis (RA), and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing nonsteroidal anti-inflammatory drug-associated gastric ulcers.
  - Vimovo should not be substituted with the single-ingredient products of naproxen and esomeprazole magnesium.
  - Vimovo is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products.
  - Controlled studies do not extend beyond 6 months.
- In addition, Vimovo's indication clarifies that the esomeprazole magnesium component is indicated to decrease the risk of developing naproxen-associated gastric ulcers.
- The new and expanded indications of Vimovo were approved based on extrapolation of adequate and well-controlled studies in adults and supported by a 6 month safety study including pharmacokinetic assessment of naproxen and esomeprazole magnesium in 36 adolescent patients with JIA.
  - Based on the limited data, the plasma naproxen and esomeprazole concentrations were found to be within the range to that observed in those found in healthy adults.
  - The safety profile of Vimovo in adolescent patients with JIA is similar to adults with RA.
- Vimovo carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- The recommended dose of Vimovo in adults and adolescent patients ≥ 12 years of age and weighing > 50 kg is one Vimovo tablet twice daily of either 375 mg naproxen/20 mg esomeprazole or 500 mg of naproxen/20 mg esomeprazole.
- The recommended dose of Vimovo in adolescent patients ≥ 12 years of age and weighing 38 kg to < 50 kg is one Vimovo tablet twice daily of 375 mg naproxen/20 mg esomeprazole.