



Relistor® (methylnaltrexone bromide) – New Formulation Approval

- On July 19, 2016, [Valeant and Progenics announced](#) the FDA approval of [Relistor \(methylnaltrexone bromide\)](#) tablets, for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain (NCP).
 - Relistor is currently available as an injection formulation.
 - Relistor injection shares the same indication as the tablet in addition to the treatment of OIC in adult patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.
 - Use of Relistor injection beyond four months has not been studied in the advanced illness population.
- The safety and efficacy of the Relistor tablet was demonstrated in a placebo-controlled study of 401 adults with chronic NCP for which they were taking opioids.
 - The Relistor treatment arm demonstrated statistically significant improvements in rescue-free bowel movement (RFBM) within 4 hours of administration over 28 days of dosing vs. placebo, achieving the primary endpoint.
 - The Relistor treatment group also had a statistically significant higher percentage of responders (defined as ≥ 3 RFBMs/week, with an increase of ≥ 1 RFBM/week from baseline for at least 3 of the 4 weeks) vs. placebo (52% vs. 38%).
- Overall, efficacy of oral Relistor in this study was comparable to that reported in clinical studies of the injectable formulation in patients with chronic NCP. The overall observed safety profile seen in patients treated with oral Relistor was comparable to placebo.
- Relistor is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.
- Other warnings and precautions of Relistor include severe or persistent diarrhea and opioid withdrawal.
- The most common adverse reactions ($\geq 2\%$) with Relistor tablet use were abdominal pain, diarrhea, headache, abdominal distention, vomiting, hyperhidrosis, anxiety, muscle spasms, rhinorrhea, and chills.
- The recommended dose of Relistor tablets is 450 mg given orally once daily on an empty stomach at least 30 minutes before the first meal of the day.
- Valeant plans to launch Relistor 150 mg tablets by the 3rd quarter of 2016.



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