



Dexlansoprazole [Dexilant™, Dexilant™ SoluTab] – Expanded Indication

- On July 11, 2016, [Takeda announced the FDA approval](#) of [dexlansoprazole](#) (Dexilant delayed-release capsules, Dexilant SoluTab orally disintegrating tablets) for the expansion of the current indications to include pediatric patients 12 to 17 years of age.
 - Previously, both formulations of Dexilant were approved only for use in adults.
- Dexilant and Dexilant SoluTab are indicated:
 - To maintain healing of erosive esophagitis (EE) and relief of heartburn for up to six months in adults and 16 weeks in patients 12 to 17 years of age.
 - For treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for four weeks.
- Dexilant delayed-release capsules are also indicated for healing of all grades of EE for up to eight weeks.
- The expanded pediatric indication for Dexilant is based on data from studies of Dexilant capsules in adults, with additional studies performed in pediatric patients.
 - In one study, a majority of patients treated with Dexilant 60 mg daily for 8 weeks experienced healing of EE [82%, n = 51/62, 95% CI: 70, 91].
 - Of the 51 patients who experienced healing of EE, 72% [n = 18/22, 95% CI: 51, 88] maintained healing of EE compared to 54% [n = 14/26, 95% CI: 33, 73] with placebo.
 - In a single-arm study, 47% of 104 pediatric patients with symptomatic non-erosive GERD experienced heartburn-free periods during a 4 week treatment period with Dexilant 30 mg capsules.
- The recommended doses of Dexilant capsules and Dexilant SoluTab for patients 12 years of age and older are as follows:
 - Maintenance of healed EE and relief of heartburn: 30 mg once daily for up to 6 months in adults and 16 weeks in patients 12 – 17 years of age.
 - Symptomatic non-erosive GERD: 30 mg once daily for 4 weeks
- The recommended dose of Dexilant capsules for the healing of EE is 60 mg once daily for up to 8 weeks.
 - Two 30 mg Dexilant SoluTab tablets are not interchangeable with one 60 mg Dexilant delayed-release capsule.
- Dexilant SoluTab is available as a 30 mg orally disintegrating tablet while the Dexilant delayed-release capsules are available as 30 mg and 60 mg capsules.



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