

FIRST TIME GENERIC APPROVAL

Brand Name	Dexilant™
Generic Name	dexlansoprazole
Drug Manufacturer	Par Pharmaceutical

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

April 19, 2017

LAUNCH DATE

January 3, 2021

REVIEW DESIGNATION

None

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 202294

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Dexlansoprazole is a proton pump inhibitor (PPI) indicated in patients 12 years of age and older for:

- Healing of all grades of erosive esophagitis (EE).
- Maintenance of healed EE and relief of heartburn.
- Treatment of symptomatic non-erosive gastroesophageal reflux disease (GERD).

MECHANISMS OF ACTION

Dexlansoprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the (H⁺, K⁺)-ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, dexlansoprazole has been characterized as a gastric proton-pump inhibitor, in that it blocks the final step of acid production.

DOSE FORM AND STRENGTH

Delayed-release capsules: 30 mg and 60 mg

DOSE & ADMINISTRATION

Recommended Dosage in Patients 12 Years of Age and Older:

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

FIRST TIME GENERIC APPROVAL

Table 1. Recommended DEXILANT Capsules Dosage Regimen by Indication in Patients 12 Years of Age and Older		
Indication	Dosage of DEXILANT Capsules	Duration
Healing of EE	One 60 mg capsule once daily.	Up to 8 weeks.
Maintenance of Healed EE and Relief of Heartburn	One 30 mg capsule once daily.	Controlled studies did not extend beyond 6 months in adults and 16 weeks in patients 12 to 17 years of age.
Symptomatic Non-Erosive GERD	One 30 mg capsule once daily.	4 weeks.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.