

FIRST TIME GENERIC APPROVAL

Brand Name	Daliresp®
Generic Name	roflumilast
Drug Manufacturer	Zydus Pharmaceuticals (USA) Inc

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

October 13, 2022

LAUNCH DATE

October 20, 2022

REVIEW DESIGNATION

Abbreviated New Drug Application (ANDA): 208303

TYPE OF REVIEW

Standard

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Roflumilast is a selective phosphodiesterase 4 inhibitor indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Limitations of Use:

- Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

MECHANISMS OF ACTION

Roflumilast and its active metabolite (roflumilast N-oxide) are selective inhibitors of phosphodiesterase 4 (PDE4). Roflumilast and roflumilast N-oxide inhibition of PDE4 (a major cyclic-3',5'-adenosine monophosphate (cyclic AMP)-metabolizing enzyme in lung tissue) activity leads to accumulation of intracellular cyclic AMP. While the specific mechanism(s) by which roflumilast exerts its therapeutic action in COPD patients is not well defined, it is thought to be related to the effects of increased intracellular cyclic AMP in lung cells.

DOSE FORM AND STRENGTH

Tablets: 500 mcg

DOSE & ADMINISTRATION

The maintenance dose for patients with COPD is one 500 mcg tablet per day, with or without food.

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.