



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Daliresp™

Common Name: roflumilast

PDL Category: Phosphodiesterase Inhibitors

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Atrovent HFA	Preferred
Spiriva	Preferred

Summary

Indications and Usage: Indicated to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Daliresp™ is not indicated for the treatment of acute bronchospasms.¹

Mechanism of Action: Selective inhibitor of phosphodiesterase 4 (PDE4) thus increasing intracellular cyclic AMP.¹

Dosage Forms: Tablets: 500mcg

Recommended Dosage: Recommended dose is 500mcg once daily, with or without food.¹

Common Adverse Drug Reactions: Diarrhea, nausea, headache, insomnia, back pain, decreased appetite, dizziness, weight loss, influenza.¹

Contraindications: Moderate to severe liver impairment.¹

Manufacturer: Forest Pharmaceuticals, Inc.

Analysis: Daliresp™ is a new oral phosphodiesterase inhibitor indicated to reduce the risk of exacerbations in a specific subset of COPD patients. In the four trials used to evaluate COPD exacerbations, 2 trials did not demonstrate a significant reduction in the rate of COPD exacerbations. From these 2 trials, a specific subpopulation of patients with chronic bronchitis and COPD exacerbations within the previous year were noted to demonstrate a response. Patients fitting this criterion, in addition to a 20 pack per year smoking history, were used to assess COPD exacerbations in 2 additional trials. These 2 trials demonstrated a significant reduction in the rate of moderate or severe exacerbations when compared to placebo. Daliresp™ is indicated only for a specific subset of COPD patients, has been linked to psychiatric adverse reactions such as depression and suicide, and interacts with CYP3A4 drugs which can increase adverse effects. Therefore, it is recommended that Daliresp™ be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Non-Preferred Drug with Conditions	

1. Daliresp™ [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; 2011.