

When clicked this will link to the Daliresp Prescribing Information from www.frx.com/pi/Daliresp\_pi.pdf

When the mouse is rolled over this button, the expansion screen opens. The expanded banner screens are shown later in this submission.

**Daliresp**  
(roflumilast) tablets  
500 mcg

**DALIRESP** represents the first class of drugs approved for COPD in 25 years<sup>1,2</sup>

Roll over to learn more

**INDICATIONS AND USAGE**  
DALIRESP is 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. DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**  
DALIRESP is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

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FULL PRESCRIBING INFORMATION

Expands the Important Safety Information

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**IMPORTANT SAFETY INFORMATION**

**Warnings and Precautions**  
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Manually scrolled Important Safety Information

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**IMPORTANT SAFETY INFORMATION**

- Prescribers should advise patients, their caregivers, and families to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood

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**IMPORTANT SAFETY INFORMATION**

changes, and if such changes occur, to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment if such events occur. Before

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using DALIRESP in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP.

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**IMPORTANT SAFETY INFORMATION**

- Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In controlled clinical trials 5.9% of patients treated with DALIRESP reported psychiatric

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adverse reactions vs 3.3% treated with placebo. The most common psychiatric adverse reactions were insomnia (2.4% vs 1.0%), anxiety (1.4% vs 0.9%), and

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depression (1.2% vs 0.9%). Three patients treated with DALIRESP experienced suicide-related adverse reactions (one completed suicide and two suicide attempts) compared

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**IMPORTANT SAFETY INFORMATION**

to one patient (suicidal ideation) treated with placebo.

- Patients should have their weight monitored regularly. If unexplained or clinically significant

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weight loss occurs, weight loss should be evaluated and treatment discontinuation considered.

- In addition to weight loss being reported as a

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common adverse reaction (7.5% of patients treated with DALIRESP vs 2.1% placebo), weight was prospectively assessed in two 1-year clinical trials. In these studies that

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compared DALIRESP to placebo, 20% vs 7% experienced moderate weight loss (5-10% of body weight) and 7% vs 2% experienced severe weight loss (>10% body weight).

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**IMPORTANT SAFETY INFORMATION**

During the follow-up period after discontinuing DALIRESP, the majority of patients regained some of the weight they had lost.

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**IMPORTANT SAFETY INFORMATION**

and may reduce the therapeutic effectiveness of DALIRESP.

**Adverse Reactions**

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**IMPORTANT SAFETY INFORMATION**

In clinical trials the most common adverse reactions (≥2% and greater than placebo) were diarrhea (9.5% vs 2.7%), weight loss (7.5% vs 2.1%), nausea (4.7% vs 1.4%), headache (4.4%

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vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

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Closes the expansion of the Important Safety Information

Manually scrolled Important Safety Information

**Daliresp** (roflumilast) tablets  
500 mcg

**IMPORTANT SAFETY INFORMATION** X

**Contraindications**  
DALIRESP is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

**Warnings and Precautions**

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- Prescribers should advise patients, their caregivers, and families to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts or other mood changes, and if such changes occur, to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment if such events occur. Before using DALIRESP in patients with a history of

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**IMPORTANT SAFETY INFORMATION** X

depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP.

- Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In controlled clinical trials 5.9% of patients treated with DALIRESP reported psychiatric adverse reactions vs 3.3% treated with placebo. The most common psychiatric adverse reactions were insomnia (2.4% vs 1.0%), anxiety (1.4% vs 0.9%), and depression (1.2% vs 0.9%). Three patients treated with DALIRESP experienced suicide-related adverse reactions (one completed suicide and two suicide attempts) compared to one patient (suicidal ideation) treated with placebo.

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**Daliresp** (roflumilast) tablets  
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**IMPORTANT SAFETY INFORMATION** X

- Patients should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated and treatment discontinuation considered.
- In addition to weight loss being reported as a common adverse reaction (7.5% of patients treated with DALIRESP vs 2.1% placebo), weight was prospectively assessed in two 1-year clinical trials. In these studies that compared DALIRESP to placebo, 20% vs 7% experienced moderate weight loss (5-10% of body weight) and 7% vs 2% experienced severe weight loss (>10% body weight). During the follow-up period after discontinuing DALIRESP, the majority of patients regained some of the weight they had lost.

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**IMPORTANT SAFETY INFORMATION** X

- Use with strong cytochrome P450 enzyme inducers (eg, rifampicin, phenobarbital, carbamazepine, phenytoin) is not recommended, as they decrease the exposure and may reduce the therapeutic effectiveness of DALIRESP.

**Adverse Reactions**  
In clinical trials the most common adverse reactions ( $\geq 2\%$  and greater than placebo) were diarrhea (9.5% vs 2.7%), weight loss (7.5% vs 2.1%), nausea (4.7% vs 1.4%), headache (4.4% vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

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These units are each sized at 728 X 90

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**INDICATIONS & USAGE AND IMPORTANT SAFETY INFORMATION** [CLICK TO EXPAND IMPORTANT SAFETY INFORMATION](#)

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The size of the expansion screen is 720 X 350

This is the expanded screen that appears when the mouse rolls over for both the 728x90 & 300x350 units

Clicking here will close the screen

The Limitations of Use and Important Safety Information are static headers

Manually scrolled Important Safety Information

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**close**

*For patients with severe COPD associated with chronic bronchitis and a history of exacerbations*

**TREAT NOW WITH DALIRESP TO REDUCE THE RISK OF EXACERBATIONS**

DALIRESP represents the first class of drugs approved for COPD in 25 years<sup>1,2</sup>

- Reduces moderate or severe exacerbations by 17% vs placebo<sup>3-5</sup>
- Effective alone or in combination with a bronchodilator<sup>3,4</sup>
- Effective in older and younger patients (>65 and 40-65 years)<sup>3,4</sup>
- Statistically significant increase in lung function (pre-bronchodilator FEV<sub>1</sub>) of 48 mL vs placebo<sup>3,5</sup>
- DALIRESP is not a bronchodilator; this increase was not clinically significant<sup>3,4</sup>

**Read additional information about DALIRESP at DalirespHCP.com**

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[References](#)   [Indications and Usage](#)   [Full Prescribing Information](#)

**Limitations of Use**  
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**IMPORTANT SAFETY INFORMATION**

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**close**

*For patients with severe COPD associated with chronic bronchitis and a history of exacerbations*

**TREAT NOW WITH DALIRESP TO REDUCE THE RISK OF EXACERBATIONS**

DALIRESP represents the first class of drugs approved for COPD in 25 years<sup>1,2</sup>

- Reduces moderate or severe exacerbations by 17% vs placebo<sup>3-5</sup>
- Effective alone or in combination with a bronchodilator<sup>3,4</sup>
- Effective in older and younger patients (>65 and 40-65 years)<sup>3,4</sup>
- Statistically significant increase in lung function (pre-bronchodilator FEV<sub>1</sub>) of 48 mL vs placebo<sup>3,5</sup>
- DALIRESP is not a bronchodilator; this increase was not clinically significant<sup>3,4</sup>

**Read additional information about DALIRESP at DalirespHCP.com**

**Daliresp** (roflumilast) tablets 500 mcg

[References](#)   [Indications and Usage](#)   [Full Prescribing Information](#)

**Limitations of Use**  
DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

**IMPORTANT SAFETY INFORMATION**

Before using DALIRESP in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with DALIRESP.

- Treatment with DALIRESP is associated with an increase in psychiatric adverse reactions. In controlled clinical trials 5.9% of patients treated with DALIRESP reported psychiatric adverse reactions vs 3.3% treated with placebo. The most common psychiatric adverse reactions were insomnia (2.4% vs 1.0%), anxiety (1.4% vs 0.9%), and depression (1.2% vs 0.9%). Three patients treated with DALIRESP experienced suicide-related

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- adverse reactions (one completed suicide and two suicide attempts) compared to one patient (suicidal ideation) treated with placebo.
- Patients should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated and treatment discontinuation considered.
- In addition to weight loss being reported as a common adverse reaction (7.5% of patients treated with DALIRESP vs 2.1% placebo), weight was prospectively assessed in two 1-year clinical trials. In these studies that compared DALIRESP to placebo, 20% vs 7% experienced moderate weight loss (5-10% of body

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- weight) and 7% vs 2% experienced severe weight loss (>10% body weight). During the follow-up period after discontinuing DALIRESP, the majority of patients regained some of the weight they had lost.
- Use with strong cytochrome P450 enzyme inducers (eg, rifampicin, phenobarbital, carbamazepine, phenytoin) is not recommended, as they decrease the exposure and may reduce the therapeutic effectiveness of DALIRESP.

**Adverse Reactions**  
In clinical trials the most common adverse reactions (≥2% and greater than placebo) were diarrhea (9.5% vs 2.7%), weight loss (7.5% vs 2.1%),

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- nausea (4.7% vs 1.4%), headache (4.4% vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

**Please see full Prescribing Information.**

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**References**

1. US Food and Drug Administration. FDA news release. March 1, 2011. <http://www.fda.gov/NewsEvents/newsroom/PressAnnouncements/ucm244989.htm>. Accessed May 22, 2012.
2. US Food and Drug Administration. Atrovent approval history (NDA 019085, 1986). Drugs@FDA. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed May 22, 2012.
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5. Calverley PMA, Rabe KF, Goehring U-M, Kristiansen S, Fabbri LM, Martinez FJ; for the M2-124 and M2-125 study groups. Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomised clinical trials. *Lancet*. 2009;374:685-694.

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**Contraindications**  
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**References**      **Indications and Usage**      **Full Prescribing Information**

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**INDICATIONS AND USAGE**  
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