

POC #4

These banner units are each 300 x 350 in size

Daliresp (roflumilast) tablets
500 mcg

What can YOU do to help the severe COPD patient (aged >65) with chronic bronchitis and a history of exacerbations?

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).

CLICK TO EXPAND IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

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

Manually scrolled Important Safety Information

Expands the Important Safety Information

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

Daliresp
(roflumilast) tablets
500 mcg

IMPORTANT SAFETY INFORMATION X

Contraindications
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Warnings and Precautions

- DALIRESP is not a bronchodilator and should not be used for the relief of acute bronchospasm.
- 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

CLICK TO CLOSE IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

Closes the expansion of the Important Safety Information

Manually scrolled Important Safety Information

This layout is to show the extended ISI copy in its entirety.

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 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 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%), 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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Links to: http://www.frx.com/pi/Daliresp_pi.pdf

These units are each sized at 728 X 90

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

Expands the Important Safety Information

Manually scrolled Important Safety Information

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500 mcg

What can YOU do to help the severe COPD patient (aged >65) with chronic bronchitis and a history of exacerbations?

[Roll over to learn more](#)

INDICATIONS & USAGE AND IMPORTANT SAFETY INFORMATION

[CLICK TO EXPAND IMPORTANT SAFETY INFORMATION](#)

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INDICATIONS & USAGE AND IMPORTANT SAFETY INFORMATION

[CLICK TO CLOSE IMPORTANT SAFETY INFORMATION](#)

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This shows the full Important Safety Information. Please note that the ISI will not spill over as it does on this example. This layout is to show you the full ISI copy in its entirety that will be visible in the scroll box.

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

The Limitations of Use and Important Safety Information are static headers

Manually scrolled Important Safety Information

These units link to the www.DalirespHCP.com website which was submitted separately as job # 84-1200028-R1.

For patients with severe COPD associated with chronic bronchitis and a history of exacerbations
THE VERY SEVERE/OLDER PATIENT

Jane, 79, likes baking with her grandchildren

- Diagnosed with COPD 15 years ago, now has very severe disease (post-bronchodilator FEV₁ 20% predicted) and chronic bronchitis
- Shortness of breath while at rest
- Frequent exacerbations each year
- Ongoing treatment with nebulized bronchodilators and oxygen

Current Status: Recently admitted to a long-term care facility

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(roflumilast) tablets
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Learn more about DALIRESP

For illustrative purposes, not an actual patient

• Full Prescribing Information • Indications and Usage

Limitations of Use
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When the mouse is rolled over this the Indications and Usage are displayed

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This screen displays the Indications and Usage text that appears when the mouse is rolled over 'Indications and Usage'

This screen shows the full Important Safety Information copy that will be in the side scroll bar

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