These banner units are each 300x350 in size

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

When the user rolls the mouse over this button the first expansion screen opens

Expands the Important Safety Information

Manually scrolled Important Safety Information

These screens show the expanded Important Safety Information when the 'CLICK TO EXPAND IMPORTANT SAFETY INFORMATION' link is clicked

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
- 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

Daliresp
(roflumilast) tablets
500 mcg

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.

CLICK TO CLOSE IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

Daliresp
(roflumilast) tablets
500 mcg

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.

CLICK TO CLOSE IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

Daliresp
(roflumilast) tablets
500 mcg

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 (≥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.

CLICK TO CLOSE IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

Daliresp
(roflumilast) tablets
500 mcg

IMPORTANT SAFETY INFORMATION X

84-12000309 9/12

Forest Laboratories, Inc.

CLICK TO CLOSE IMPORTANT SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

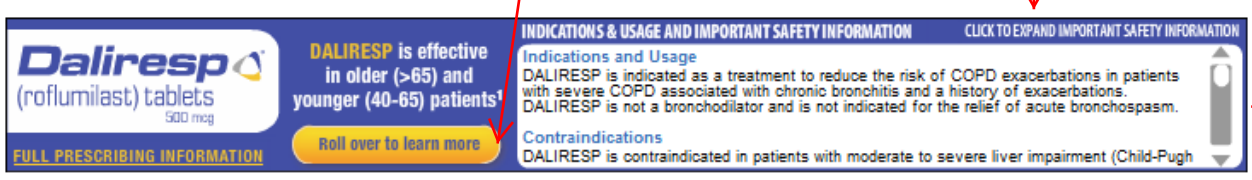
These banner units are each sized at 728 X 90

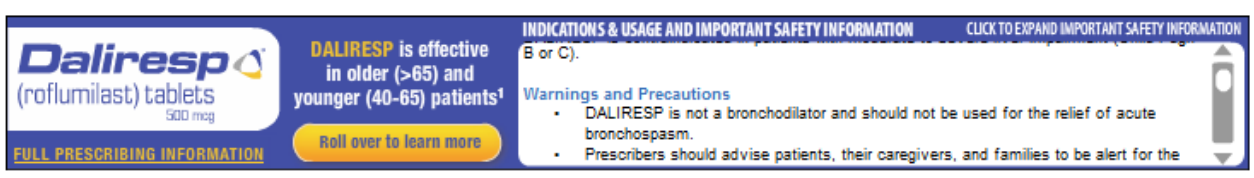
When the mouse is rolled over this button, the expansion screen opens

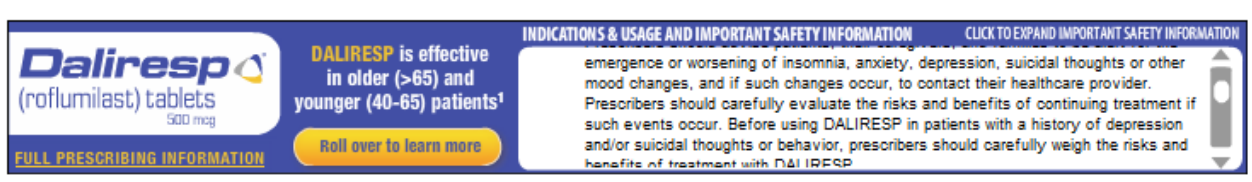
Expands the Important Safety Information

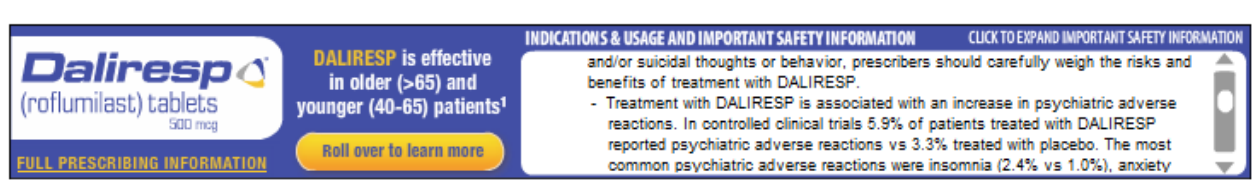
When clicked this will link to the Daliresp Prescribing Information from www.frx.com/pi/Daliresp_pi.pdf

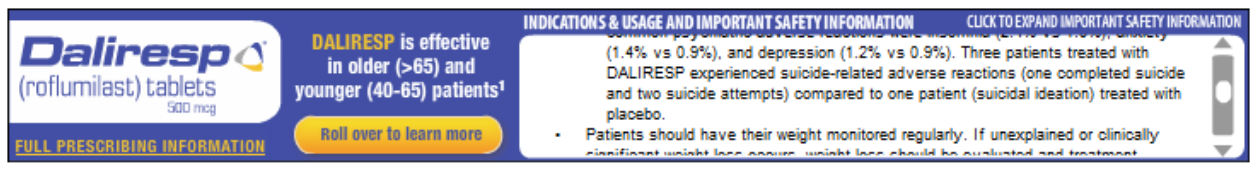
Manually scrolled Important Safety Information

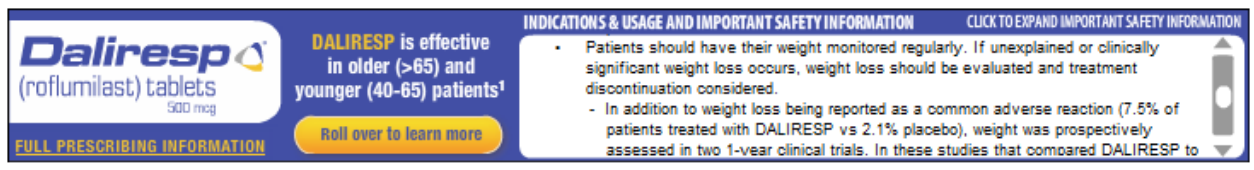


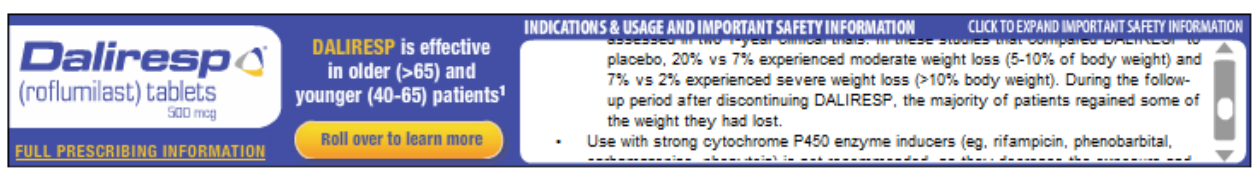


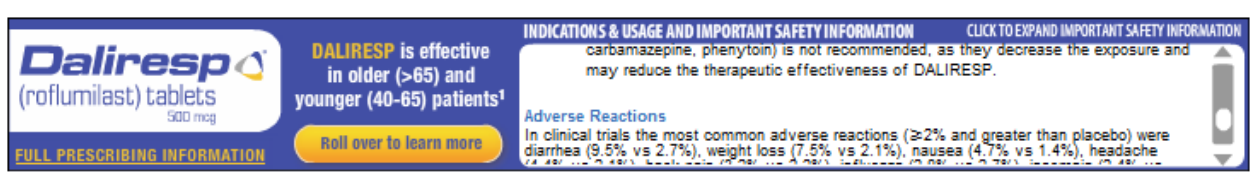


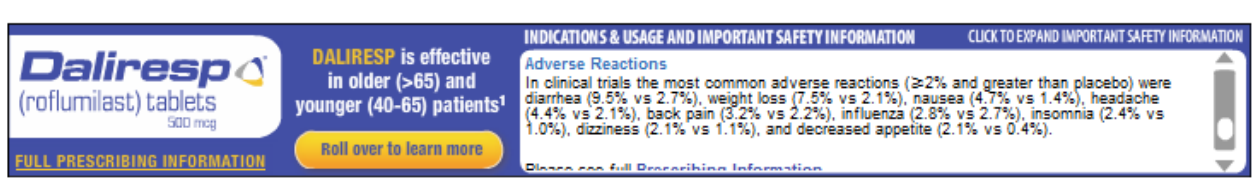


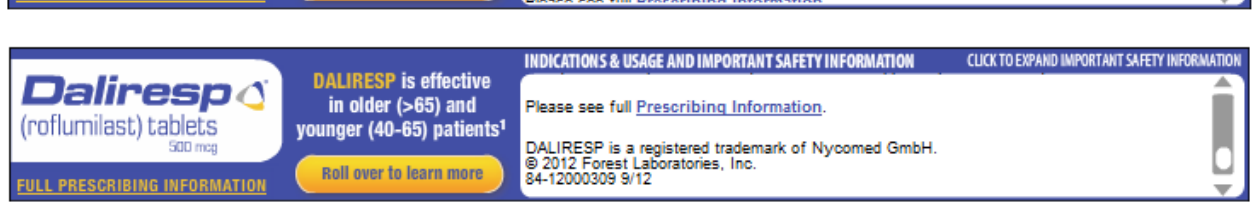








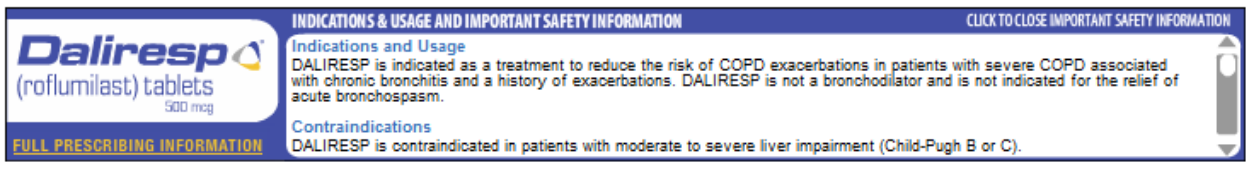


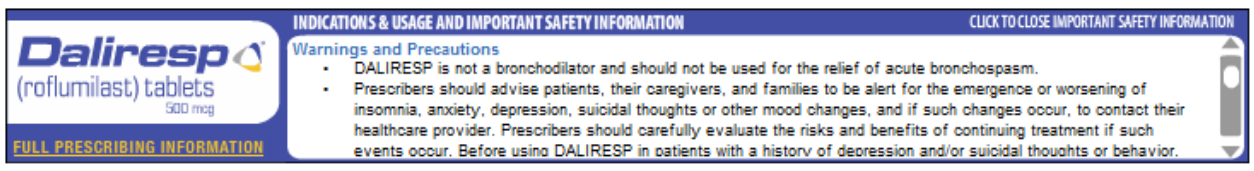


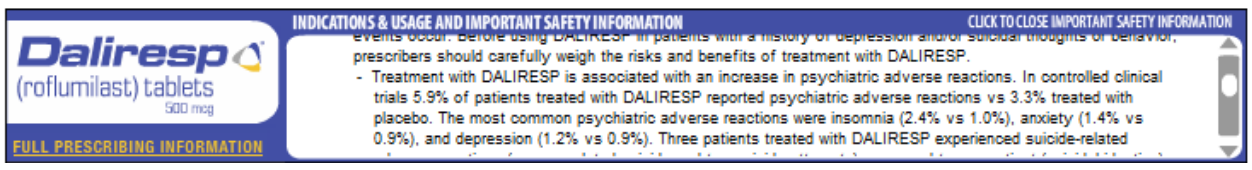
These screens show the expanded Important Safety Information when the 'CLICK TO EXPAND IMPORTANT SAFETY INFORMATION' link is clicked

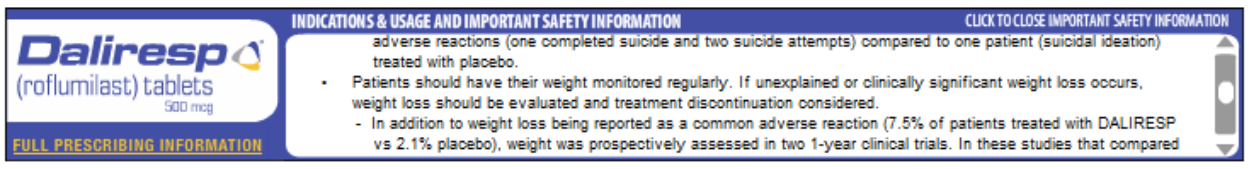
Closes the expansion of the Important Safety Information

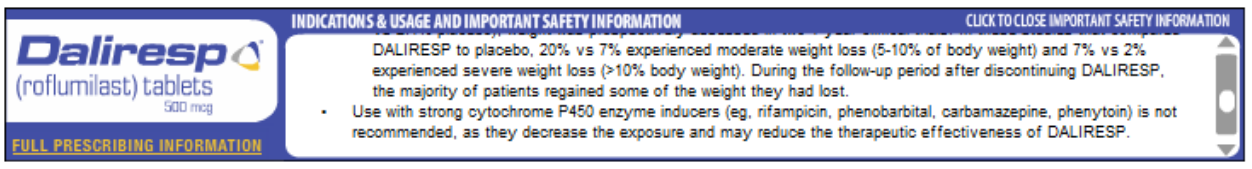
Manually scrolled Important Safety Information

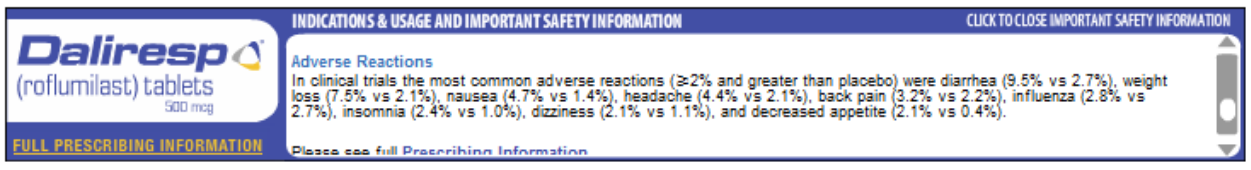


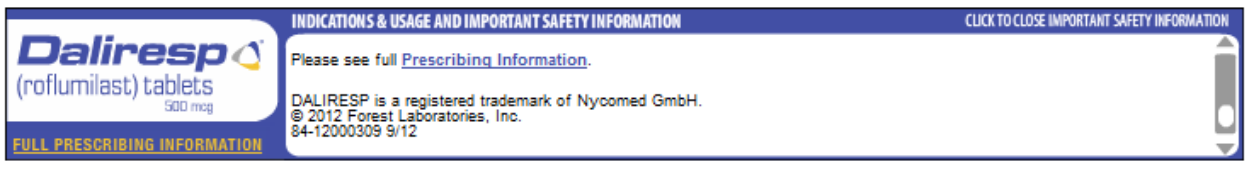












The size of the expansion screen is 720 X 350

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

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

When clicked this will take the user to the second expansion screen

When clicked the graphic will enlarge to about twice this size

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 the study design is displayed

When the mouse is rolled over this the references used in this banner unit are displayed

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

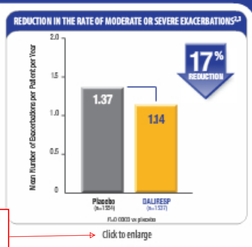
close

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

DALIRESP SIGNIFICANTLY REDUCES EXACERBATIONS

DALIRESP significantly reduced the rate of moderate or severe exacerbations by 17%[2,3]

- Moderate exacerbations were defined as those requiring treatment with systemic corticosteroids[1]
- Severe exacerbations were defined as resulting in hospitalization and/or death[1]
- DALIRESP is effective in older and younger patients (>65 and 40-65 years)[1]
- Greater sensitivity of some older individuals cannot be ruled out[1]



Click to enlarge

Read additional information about DALIRESP at DaliespHCP.com

Review study data for DALIRESP in older and younger patients

Daliresp (roflumilast) tablets 500 mcg

Study Design | 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

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.

close

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

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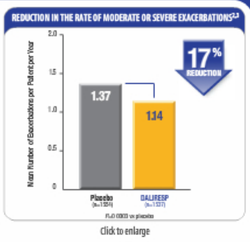

Click to enlarge

Read additional information about DALIRESP at DaliespHCP.com

Review study data for DALIRESP in older and younger patients

Daliresp (roflumilast) tablets 500 mcg

Study Design | 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

close

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

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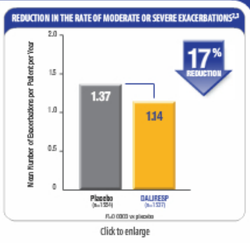

Click to enlarge

Read additional information about DALIRESP at DaliespHCP.com

Review study data for DALIRESP in older and younger patients

Daliresp (roflumilast) tablets 500 mcg

Study Design | References | Indications and Usage | Full Prescribing Information

Limitations of Use
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IMPORTANT SAFETY INFORMATION
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

close

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

DALIRESP SIGNIFICANTLY REDUCES EXACERBATIONS

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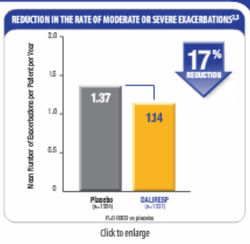
- Greater sensitivity of some older individuals cannot be ruled out[1]



Click to enlarge

Read additional information about DALIRESP at DaliespHCP.com

Review study data for DALIRESP in older and younger patients

Daliresp (roflumilast) tablets 500 mcg

Study Design | References | Indications and Usage | Full Prescribing Information

Limitations of Use
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IMPORTANT SAFETY INFORMATION
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%),

close

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

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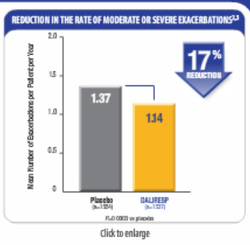

Click to enlarge

Read additional information about DALIRESP at DaliespHCP.com

Review study data for DALIRESP in older and younger patients

Daliresp (roflumilast) tablets 500 mcg

Study Design | References | Indications and Usage | Full Prescribing Information

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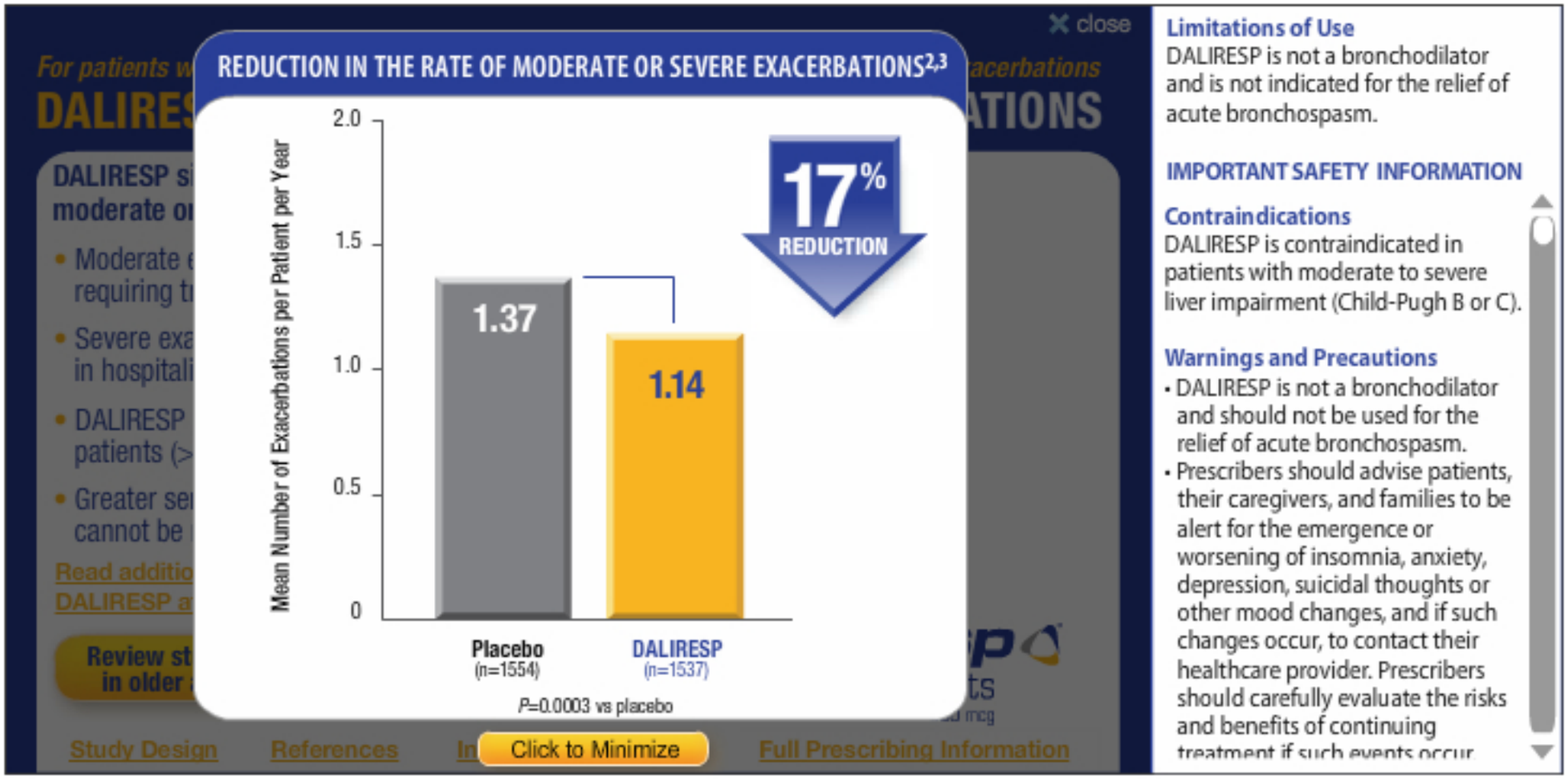
IMPORTANT SAFETY INFORMATION
nausea (4.7% vs 1.4%), headache (4.4% vs 2.1%), back pain (3.2% vs 2.2%), influenza (2.8% vs 2.7%), insomnia (2.4% vs 1.0%), dizziness (2.1% vs 1.1%), and decreased appetite (2.1% vs 0.4%).

Please see full Prescribing Information.

Forest Laboratories, Inc.

This screen shows how the 'Click to Enlarge' button displays the graphic



Manually scrolled Important Safety Information

When clicked this button will bring the graphic back to its original size

This screen displays the Study design text that appears when the mouse is rolled over 'Study Design'

close

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

DALIRESP SIGNIFICANTLY REDUCES EXACERBATIONS

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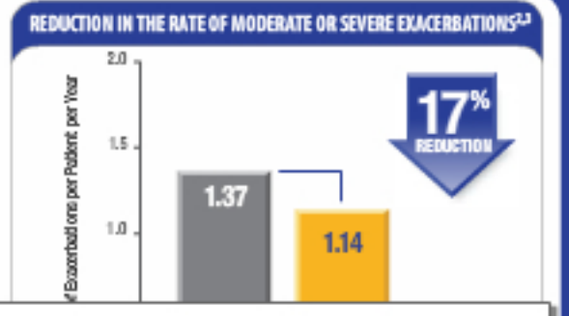

Study design
A pre-specified pooled analysis from 2 identical, 52-week, double-blind, placebo-controlled trials in patients with severe COPD associated with chronic bronchitis and a history of exacerbations (N=3091). Median patient age was 64 years; 76% male, 84% Caucasian. LABAs or short-acting anticholinergics were allowed as concomitant treatment. The reduction in the rate of moderate (requiring treatment with systemic glucocorticosteroids) or severe (resulting in hospitalization and/or leading to death) exacerbations and change in lung function (pre-bronchodilator FEV_1) were co-primary endpoints. Each study met both co-primary endpoints.

Study Design | References | Indications and Usage | Full Prescribing Information

Limitations of Use
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IMPORTANT SAFETY INFORMATION

Contraindications
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Warnings and Precautions
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Manually scrolled Important Safety Information

This screen displays the references that appear when the mouse is rolled over 'References'

close

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

DALIRESP SIGNIFICANTLY REDUCES EXACERBATIONS

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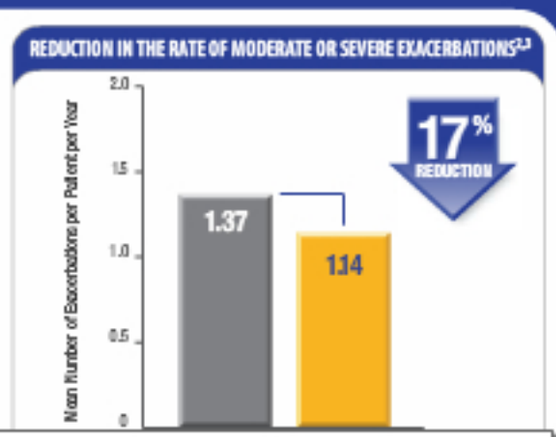
- Greater sensitivity of some older individuals



References

1. DALIRESP (roflumilast) Prescribing Information. Forest Pharmaceuticals, Inc. St. Louis, MO.
2. Data on file. Forest Laboratories, Inc.
3. 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.

Study Design | References | Indications and Usage | Full Prescribing Information

Limitations of Use

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IMPORTANT SAFETY INFORMATION

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Manually scrolled Important Safety Information

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

close

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

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DALIRESP significantly reduced the rate of moderate or severe exacerbations by 17%[2,3]

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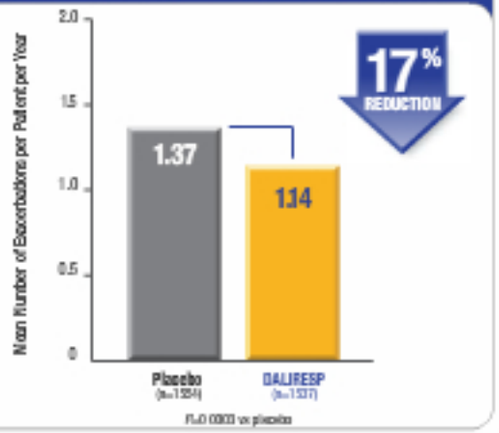
- Greater sensitivity of some older individuals cannot be ruled out[1]

REDUCTION IN THE RATE OF MODERATE OR SEVERE EXACERBATIONS[2,3]



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.

Study Design | References | Indications and Usage | Full Prescribing Information

Limitations of Use
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IMPORTANT SAFETY INFORMATION

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Warnings and Precautions
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Manually scrolled Important Safety Information

This is the second expansion screen

Clicking here will close the screen

close

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

DALIRESP IS EFFECTIVE IN OLDER AND YOUNGER PATIENTS

No overall differences in safety or effectiveness were observed between older and younger patients[1]

CONSISTENT EFFECT ACROSS AGE GROUPS[1]

YOUNGER: 40-65 Years of Age	✓
OLDER: >65 Years of Age	✓

- Greater sensitivity of some older individuals cannot be ruled out[1]
- No dosage adjustment is necessary for geriatric patients[1]
- The safety and effectiveness of DALIRESP in pediatric patients have not been established[1]

Back to DALIRESP Significantly Reduces Exacerbations

Read additional information about DALIRESP at DaliespHCP.com

Daliresp® (roflumilast) tablets 500 mcg

Study Design 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

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

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When clicked the user will be taken to the previous expansion screen

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

When the mouse is rolled over this the study design is displayed

When the mouse is rolled over this the references used in this banner unit are displayed

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

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

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Study design
Analysis reflects exposure of 4438 patients to DALIRESP 500 mcg once daily in four 1-year placebo-controlled trials, two 6-month placebo controlled trials, and two 6-month add-on trials. Of the 4438 COPD subjects exposed to DALIRESP for up to 12 months in 8 controlled clinical trials, 2022 were >65 years of age and 471 were >75 years of age.

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This screen displays the references that appear when the mouse is rolled over 'References'

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References

1. DALIRESP (roflumilast) Prescribing Information. Forest Pharmaceuticals, Inc. St. Louis, MO.
2. Data on file. Forest Laboratories, Inc.
3. 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.

Study Design | References | Indications and Usage | Full Prescribing Information

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Back to DALIRESP Significantly Reduces Exacerbations

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.

Study Design | References | Indications and Usage | Full Prescribing Information

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