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MEDICATION GUIDE
DALIRESP® (da'-li-resp)
(roflumilast)
Tablets

Read this Medication Guide before you start taking DALIRESP® and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about DALIRESP?

DALIRESP can cause serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while taking DALIRESP.

- 1. DALIRESP may cause mental health problems including suicidal thoughts and behavior.** Some people taking DALIRESP may develop mood or behavior problems including:
 - thoughts of suicide or dying
 - attempt to commit suicide
 - trouble sleeping (insomnia)
 - new or worse anxiety
 - new or worse depression
 - acting on dangerous impulses
 - other unusual changes in your behavior or mood

- 2. Weight loss.** DALIRESP can cause weight loss. You should check your weight on a regular basis. You will also need to see your healthcare provider regularly to have your weight checked. If you notice that you are losing weight, call your healthcare provider. Your healthcare provider may ask you to stop taking DALIRESP if you lose too much weight.

DALIRESP may affect the way other medicines work, and other medicines may affect how DALIRESP works. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

What is DALIRESP?

DALIRESP is a prescription medicine used in adults with severe Chronic Obstructive Pulmonary Disease (COPD) to decrease the number of flare-ups or the worsening of COPD symptoms (exacerbations).

DALIRESP is not a bronchodilator and should not be used for treating sudden breathing problems. Your healthcare provider may give you other medicine to use for sudden breathing problems.

It is not known if DALIRESP is safe and effective in children.

Who should not take DALIRESP?

Do not take DALIRESP if you:

- have certain liver problems. Talk with your healthcare provider before you take DALIRESP if you have liver problems.

What should I tell my healthcare provider before taking DALIRESP?

Before you take DALIRESP, tell your healthcare provider if you:

- have or have had a history of mental health problems including depression and suicidal behavior.
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if DALIRESP will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

- 661 • are breastfeeding or plan to breastfeed. It is not known if DALIRESP passes into your breast milk. You and your
662 healthcare provider should decide if you will take DALIRESP or breastfeed. You should not do both.

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664 **How should I take DALIRESP?**

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- 666 • Take DALIRESP exactly as your healthcare provider tells you to take it.
667 • DALIRESP can be taken with or without food.
668 • If you take more than your prescribed dose of DALIRESP, call your healthcare provider or go to the nearest hospital
669 emergency room right away.

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671 **What are the possible side effects of DALIRESP?**

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673 **DALIRESP can cause serious side effects, including:**

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675 See **“What is the most important information I should know about DALIRESP?”**

676 **The most common side effects of DALIRESP include:**

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- 678 • diarrhea
679 • weight loss
680 • nausea
681 • headache
682 • back pain
683 • flu like symptoms
684 • problems sleeping (insomnia)
685 • dizziness
686 • decreased appetite

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688 Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

689 These are not all the possible side effects of DALIRESP.

690 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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692 **How do I store DALIRESP Tablets?**

- 693 • **Store DALIRESP at 68°F to 77°F (20°C to 25°C)** ; excursions permitted to 15° - 30°C (59° - 86°F). [See USP
694 Controlled Room Temperature].

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696 **Keep DALIRESP Tablets and all medicines out of the reach of children.**

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698 **General information about DALIRESP**

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700 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DALIRESP for a
701 condition for which it was not prescribed. Do not give DALIRESP to other people, even if they have the same symptoms that
702 you have. It may harm them.

703 This Medication Guide summarizes the most important information about DALIRESP. For more information about
704 DALIRESP, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about
705 DALIRESP that is written for health professionals.

706 For more information about DALIRESP call 1-800-678-1605.

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708 **What are the ingredients in DALIRESP?**

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710 **Active ingredient:** roflumilast

711 **Inactive ingredients:** lactose monohydrate, corn starch, povidone and magnesium stearate.

712

713 Rx only

714 Manufactured by:

715 Nycomed GmbH

716 Production Site Oranienburg
717 Lehnitzstrasse 70 – 98
718 16515 Oranienburg
719 Germany

720
721 Manufactured for:
722 Forest Pharmaceuticals, Inc.
723 Subsidiary of Forest Laboratories, Inc.
724 St. Louis, MO 63045, USA
725

726 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

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