

MEDICATION GUIDE
Roflumilast Tablets (rō-FLOO-meh-last)

Read this Medication Guide before you start taking roflumilast tablets 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 roflumilast tablets?

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

- 1. Roflumilast tablets may cause mental health problems including suicidal thoughts and behavior.** Some people taking roflumilast tablets 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.** Roflumilast tablets 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 roflumilast tablets if you lose too much weight.

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

What are roflumilast tablets?

Roflumilast tablets are 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).

Roflumilast 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 roflumilast tablets are safe and effective in children.

Who should not take roflumilast tablets?

Do not take roflumilast tablets if you:

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

What should I tell my healthcare provider before taking roflumilast tablets?

- Before you take roflumilast tablets, 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 roflumilast will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
 - are breastfeeding or plan to breastfeed. It is not known if roflumilast passes into your breast milk. You and your healthcare provider should decide if you will take roflumilast tablets or breastfeed. You should not do both.

How should I take roflumilast tablets?

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

What are the possible side effects of roflumilast tablets?

Roflumilast tablets can cause serious side effects, including:

See **“What is the most important information I should know about roflumilast tablets?”**

The most common side effects of roflumilast tablets include:

- diarrhea
- weight loss
- nausea
- headache
- back pain
- flu like symptoms
- problems sleeping (insomnia)
- dizziness
- decreased appetite

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

These are not all the possible side effects of roflumilast tablets.

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

How do I store roflumilast tablets?

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

Keep roflumilast tablets and all medicines out of the reach of children.

General information about roflumilast tablets

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

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

For more information about roflumilast tablets go to www.amicipharma.com or call 1-866-760-2646.

What are the ingredients in roflumilast tablets?

Active ingredient: roflumilast
Inactive ingredients: lactose monohydrate, magnesium stearate, and pregelatinized starch.
Yellow iron oxide is present in the 250 mcg tablet.

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

Distributed By:
Amici Pharma, Inc.
Melville, NY 11747
Code. L7185/00
Rev # 11/2025