

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.

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.

- 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

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

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).

It is not known if roflumilast tablets are safe and effective in children.

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

- 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 tablets 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.

- Take roflumilast tablets exactly as your healthcare provider tells you to take it.

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

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

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

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

For more information about roflumilast tablets
call 1-800-912-9561.

Inactive ingredients: carboxymethyl cellulose calcium, lactose monohydrate, magnesium stearate, maize starch and polyvinyl alcohol.

Manufactured for:
Torrent Pharma INC.
Basking Ridge, NJ 07920.

Revised: July 2026

PRODUCT NAME :	Roflumilast Tablets	COUNTRY : US	LOCATION : Indrad			Supersedes A/W No.: 8090450
ITEM / PACK :	Medication Guide	NO. OF COLORS: 1	REMARK : SUBSTRATE :			
DESIGN STYLE :	Front/ Back	PANTONE SHADE NOS.:				
CODE :	8099471	 Black	Activities	Department	Name	Signature & Date
DIMENSIONS (MM) :	150 x 200		Prepared By	Pkg.Dev		
ART WORK SIZE :	S/S		Reviewed By	Pkg.Dev		
DATE :	04-07-2026	Font size 10 pt	Reviewed By	Quality		
			Approved By	Quality		