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Roflumilast

pronounced as (roe flue' mi last)

Why is this medication prescribed?

Roflumilast is used in people with severe chronic obstructive pulmonary disease (COPD; a group of diseases that affect the lungs and airways) to reduce the number of episodes or worsening of COPD symptoms. Roflumilast is in a class of medications called phosphodiesterase inhibitors. It works by decreasing swelling in the lungs.

How should this medicine be used?

Roflumilast comes as a tablet to take by mouth. It is usually taken with or without food once a day. Take roflumilast at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take roflumilast exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not use roflumilast to treat sudden attacks of breathing problems. Talk to your doctor about the use of other medications to treat symptoms of a sudden breathing problem.

Roflumilast may control COPD but does not cure it. Continue to take roflumilast even if you feel well. Do not stop taking roflumilast without talking to your doctor.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with roflumilast and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the manufacturer's website to obtain the Medication Guide.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking roflumilast,

- tell your doctor and pharmacist if you are allergic to roflumilast, any other medications, or any of the ingredients in roflumilast tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: carbamazepine (Tegretol), cimetidine (Tagamet), enoxacin (not available in the U.S.), erythromycin (E.E.S., E-Mycin, Erythrocin), fluvoxamine, ketoconazole (Nizoral), phenobarbital, phenytoin (Dilantin), rifampicin and certain oral contraceptives ('birth control pills'). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have liver disease. Your doctor may tell you not to take roflumilast.
- tell your doctor if you have or have ever had a history of mental health conditions, including depression; thoughts about harming or killing yourself, or planning or trying to do so; extreme worry; or other unusual changes in your behavior or mood. Talk to your doctor about the risks of taking roflumilast.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking Roflumilast, call your doctor.
- you should know that your mental health may change in unexpected ways during treatment with roflumilast. You, your family, or your caregiver should call your doctor right away if you experience any of the following new symptoms or a worsening of these symptoms: difficulty falling asleep or staying asleep; depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; or changes in mood. Be sure that your family or caregiver know these symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.
- you should know that roflumilast can cause weight loss. Your weight should be checked regularly by your doctor and you should also check your weight on a regular basis during treatment with roflumilast. If you notice you are losing weight, call your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Roflumilast may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- nausea
- dizziness
- headache
- back pain
- muscle spasm
- decrease in appetite

- uncontrollable shaking of a part of your body

Some side effects can be serious. If you experience any of the symptoms listed in the SPECIAL PRECAUTIONS section, call your doctor immediately.

Roflumilast may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- headache
- dizziness
- lightheadedness
- cold, clammy skin
- fast heart beat

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Daliresp[®]

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