



#### Package leaflet: Information for the user

### Roflumilast 500 micrograms Tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Roflumilast tablets are and what they are used for
2. What you need to know before you take Roflumilast tablets
3. How to take Roflumilast tablets
4. Possible side effects
5. How to store Roflumilast tablets
6. Contents of the pack and other information

#### 1. What Roflumilast tablets are and what they are used for

Roflumilast tablet contains the active substance roflumilast, which is an anti-inflammatory medicine called phosphodiesterase-4 inhibitor. Roflumilast reduces the activity of phosphodiesterase-4, a protein occurring naturally in body cells. When the activity of this protein is reduced, there is less inflammation in the lungs. This helps to stop narrowing of airways occurring in **chronic obstructive pulmonary disease (COPD)**. Thus roflumilast eases breathing problems.

Roflumilast is used for maintenance treatment of severe COPD in adults who in the past had frequent worsening of their COPD symptoms (so-called exacerbations) and who have chronic bronchitis. COPD is a chronic disease of the lungs that results in tightening of the airways (obstruction) and swelling and irritation of the walls of the small air passages (inflammation). This leads to symptoms such as coughing, wheezing, chest tightness or difficulty in breathing. Roflumilast is to be used in addition to bronchodilators.

#### 2. What you need to know before you take Roflumilast tablets

##### Do not take Roflumilast tablets

- if you are allergic to roflumilast or any of the other ingredients of this medicine (listed in section 6)
- if you have moderate or severe liver problems

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Roflumilast tablets.

##### Sudden attack of breathlessness

Roflumilast is not intended for the treatment of a sudden attack of breathlessness (acute bronchospasms). In order to relieve a sudden attack of breathlessness it is very important that your doctor provides you with another medicine to be available to you at all times that can cope with such an attack. Roflumilast will not help you in this situation.

##### Body weight

You should check your body weight on a regular basis. Talk to your doctor if, while taking this medicine, you observe an unintentional loss of body weight (not related to a diet or exercise programme).

##### Other diseases

Roflumilast is not recommended if you have one or more of the following diseases:

- severe immunological diseases such as HIV infection, multiple sclerosis (MS), lupus erythematosus (LE) or progressive multifocal leukoencephalopathy (PML)
- severe acute infectious diseases such as acute hepatitis
- cancer (except basal-cell carcinoma, a slow-growing type of skin cancer)
- or severe impairment of the heart function

There is a lack of relevant experience with Roflumilast under these conditions. You should talk to your doctor, if you are diagnosed with any of these diseases.

Experience is also limited in patients with a previous diagnosis of tuberculosis, viral hepatitis, herpes viral infection or herpes zoster. Please talk to your doctor if you have one of these diseases.

##### Symptoms you should be aware of

You may experience diarrhoea, nausea, abdominal pain or headache during the first weeks of treatment with Roflumilast. Talk to your doctor if these side effects do not resolve within the first weeks of treatment.

Roflumilast is not recommended in patients with a history of depression associated with suicidal thinking or behaviour. You may also experience sleeplessness, anxiety, nervousness, or depressive mood. Before starting treatment with Roflumilast, inform your doctor if you are suffering from any symptoms of this kind and of any additional medicines you may take since some of those could increase the probability of these side effects. You or your caregiver should also immediately inform your doctor of any changes in behaviour or mood and of any suicidal thoughts you may have.

##### Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age.

##### Other medicines and Roflumilast tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially the following:

- a medicine containing theophylline (a medicine to treat respiratory diseases), or
- a medicine used for treatment of immunological diseases, such as methotrexate, azathioprine, infliximab, etanercept, or oral corticosteroids to be taken long-term.
- a medicine containing fluvoxamine (a medicine to treat anxiety disorders and depression), enoxacin (a medicine to treat bacterial infections) or cimetidine (a medicine to treat stomach ulcers or heartburn).

The effect of Roflumilast may be reduced if taken together with rifampicin (an antibiotic medicine) or with phenobarbital, carbamazepine or phenytoin (medicines usually prescribed for the treatment of epilepsy). Ask your doctor for advice.

Roflumilast tablets may be taken with other medicines used in the treatment of COPD such as inhaled or oral corticosteroids or bronchodilators. Do not stop taking these medicines or reduce their dose unless advised by your doctor.

##### Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not become pregnant during treatment with this medicine and should use an effective method of contraception during therapy, because roflumilast may be harmful for the unborn baby.

##### Driving and using machines

Roflumilast has no influence on the ability to drive and use machines.

##### Roflumilast tablet contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3. How to take Roflumilast tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- **For the first 28 days** - the recommended starting dose is one 250 micrograms tablet once daily.
- The starting dose is a low dose used to help your body get used to the medicine before you start taking the full dose. At this low dose you will not get the full effect from the medicine – therefore it is important that you move on to the full dose (called a ‘maintenance dose’) after 28 days.
- **After 28 days** - the recommended maintenance dose is one 500 micrograms tablet once daily.

Swallow the tablet with some water. You may take this medicine with or without food. Take the tablet at the same time every day.

You may need to take roflumilast for several weeks to achieve its beneficial effect.

##### If you take more Roflumilast tablets than you should

If you have taken more tablets than you should, you may experience the following symptoms: headache, nausea, diarrhoea, dizziness, throbbing of your heart, light-headedness, clamminess and low blood pressure. Tell your doctor or pharmacist straight away. If possible take your medicine and this leaflet with you.

#### **If you forget to take Roflumilast tablets**

If you forget to take a tablet at the usual time, take the tablet as soon as you remember on the same day. If on one day you have forgotten to take a tablet of roflumilast, just carry on the next day with the next tablet as usual. Continue taking your medicine at the usual times. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Roflumilast tablets**

It is important to continue taking Roflumilast tablets for as long as prescribed by your doctor, even when you have no symptoms, in order to maintain control of your lung function.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience diarrhoea, nausea, stomach ache or headache during the first weeks of treatment with roflumilast. Talk to your doctor if these side effects do not resolve within the first weeks of treatment.

Some side effects could be serious. In clinical studies and post-marketing experience, rare instances of suicidal thinking and behaviour (including suicide) were reported. Please notify your doctor immediately of any suicidal thoughts you may have. You may also experience sleeplessness (common), anxiety (uncommon), nervousness (rare), panic attack (rare) or depressive mood (rare).

In uncommon cases allergic reactions may occur. Allergic reactions may affect the skin and in rare cases cause swelling of the eyelids, face, lips and tongue, possibly leading to difficulties in breathing and/or a drop in blood pressure and accelerated heartbeat. In case of an allergic reaction, stop taking Roflumilast tablets and contact your doctor immediately, or go immediately to the emergency department in the nearest hospital. Take all your medicines and this leaflet with you and provide full information of your current medications.

Other side effects include the following:

##### **Common side effects (may affect up to 1 in 10 people)**

- diarrhoea, nausea, stomach ache
- weight decrease, decreased appetite
- headache

##### **Uncommon side effects (may affect up to 1 in 100 people)**

- trembling, sensation of spinning head (vertigo), dizziness
- sensation of rapid or irregular heartbeat (palpitations)
- gastritis, vomiting
- reflux of stomach acid to the gullet (acid regurgitations), indigestion
- rash
- muscle pain, muscle weakness or cramps
- back pain
- feeling of weakness or tiredness, feeling unwell

##### **Rare side effects (may affect up to 1 in 1,000 people)**

- male breast enlargement
- decreased sense of taste
- respiratory tract infections (excluding pneumonia)
- bloody stools, constipation
- elevation of liver or muscle enzymes (seen in blood tests)
- wheals (urticaria)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Roflumilast tablets**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### **6. Contents of the pack and other information**

##### **What Roflumilast tablet contains**

The active substance is roflumilast.

Each Roflumilast 500 micrograms tablet contains 500 micrograms roflumilast. The other ingredients are lactose monohydrate, maize starch, hyperomellose, poloxamer (type 188) and magnesium stearate.

##### **What Roflumilast tablets look like and contents of the pack**

Roflumilast 500 micrograms tablets are white to off-white, flat faced bevelled edged uncoated tablets, debossed with "T" and "500" on one side and plain on the other side.

Roflumilast 500 micrograms tablets are available in blister pack (i.e. clear PVC/PVdC - Aluminium foil blister pack)

Blister pack sizes: 30 tablets

##### **Marketing Authorisation Holder**

Milpharm Limited  
Ares Block  
Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

##### **Manufacturer**

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far,  
Birzebbugia, BBG 3000, Malta

Or

Milpharm Limited  
Ares Block, Odyssey Business Park, West End Road,  
Ruislip, HA4 6QD, United Kingdom

Or

Generis Farmacêutica, S.A.,  
Rua João de Deus, n.º 19, Venda Nova, 2700-487  
Amadora, Portugal

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