



# Drug Information Bulletin

**Drug Information Centre (DIC)**

Indian Pharmaceutical Association

Bengal Branch

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**Regulatory Affairs Division (RAD), IPA**



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## Editorial

India accounts for 21 % of the total global TB burden i.e. 1.9 million new cases annually joining to the existing masses. Like the rest of the world Drug resistance TB cases are also rising in India. Presently 2-3 % of TB cases are MDR TB cases in India. Resistance are developing due to several reasons, one of them irrational prescribing of antitubercular medicines. One of the studies by Mishra G et al published recently in NJIRM may be an eye opener for the prescribers and the health policy makers of India.

Under this situation Central TB Division, Government of India has realized that services of Pharmacist required to be utilized in RNTCP programme and signed a MOU with IPA, SEARPharm Forum, PCI, AIOCD with an objective to strengthen the Revised National Tuberculosis Control Programme (RNTCP) by engaging pharmacists in RNTCP for TB Care & Control in India. Engaging Pharmacists' in TB programme was initiated in Mumbai by Indian Pharmaceutical Association (IPA) in the last decade through a pilot project which was implemented some other states of India. This model was successful and several countries expressed to follow this model in their country. In the mean time WHO signed a MOU with FIP on the role of Pharmacists in Tuberculosis care and control in the year of 2011 during FIP Congress at Hyderabad, India. Thereafter SEARPharm Forum has published a document "Compilation of a reference document of pharmacists innovative approaches to target early detection, delivery of dots, rational use, public education in TB care and Control in India [http://www.searpharm.org/resources/PDF\\_files/REPORT%20final.pdf](http://www.searpharm.org/resources/PDF_files/REPORT%20final.pdf) . In order to engage community pharmacists in Tuberculosis care and control under RNTCP a training module has been developed jointly by Central TB Division, Govt. of India and Indian Pharmaceutical Association and published it in the year of 2013. This initiative is a unique one in expanding the scope of pharmacist's role in health care system in India [www.tbcindia.nic.in/pdfs/MODULAR%20TRAINING%20a.pdf](http://www.tbcindia.nic.in/pdfs/MODULAR%20TRAINING%20a.pdf) . Unfortunately this approach has not been implemented throughout the country. Hope CTD and professional organizations will take necessary steps for its proper implementation for the sake of public health.

**Dr. Subhash C. Mandal**

Editor



## New Drug: Roflumilast

### 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 [at <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). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

#### In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local 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. Ref.:

<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a611034.html>

*(Roflumilast Tablet 500 mcg has been approved by CDSCO on 17.07.2014 for the treatment of severe chronic obstructive pulmonary disease (COPD)(FEV1 postbronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.)*

### **Australians face drug-price hike under new government rules**

The Australian government is replacing a 15% markup for pharmacists with a flat handling fee, which will increase consumer prices for antibiotics, blood-pressure medications and hundreds of other widely used drugs. Prices for many drugs may fall next year, though, when the government uses a new calculation for generics. Drug makers will face a mandatory 5% price cut after a medication has been subsidized for five years.

For details: [News.com.au \(Australia\)](http://News.com.au)

### **Proposed German bribery law could pose challenges for medtech firms**

A proposed change to the German criminal code, designed to combat bribery, could potentially affect certain types of cooperation among medtech companies and health care professionals that are currently legitimate. Medtech companies and health care professionals convicted of bribery would face fines or up to three years in prison.

For details: [Clinica](http://Clinica)

## **Forthcoming Event**

# **IPA CONVENTION 2015**

Venue: Hotel Trident, BKC, Mumbai

**Date: 05-06 June 2015**

**Theme: Indian Pharma Inc.:  
Adapting to the  
Rapidly Evolving Global  
Challenges**

### **Registration Fees:**

IPA Non Member: Rs. 12000 per person

IPA Member: Rs 10000 per person

Academia Member: Rs. 8000 per person

For details: [www.ipapharma.org](http://www.ipapharma.org)

## **IPA Bengal Branch**

**Interaction on Pharmacy  
Practice Regulation 2015**

**Venue:** IPA Auditorium, 29 B Panchanontola Road, Kolkata-700029

**Date:** 13.05.2015

**Time:** 5.00 pm