

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

DAXAS[®]

roflumilast film-coated tablets

This leaflet is part III of a three-part "Product Monograph" published when DAXAS[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DAXAS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

DAXAS is an anti-inflammatory medicine taken orally to treat chronic obstructive pulmonary disease (COPD) in adults with a history of chronic coughing with phlegm and frequent flare-ups. DAXAS is only used in addition to a bronchodilator medication. COPD is a progressive condition that causes tightening (narrowing) of breathing tubes (airways), and swelling and irritation (inflammation) of the walls of the small airways deep inside the lungs. Ongoing obstruction and inflammation in airways leads to symptoms such as coughing, wheezing, chest tightness or difficulty in breathing that get worse over time. Patients with COPD also have flare-ups (exacerbations) where symptoms suddenly get worse. Additional medications, emergency visits or hospitalization may be required to treat flare-up episodes.

What it does:

DAXAS contains the active substance roflumilast, which is an anti-inflammatory medicine called a phosphodiesterase 4 inhibitor. DAXAS reduces the activity of phosphodiesterase 4, which results in less inflammation in the lungs. This helps to stop the narrowing of airways which occurs in COPD.

When it should not be used:

Do not take DAXAS if:

- you are allergic (hypersensitive) to roflumilast or any of the other ingredients of DAXAS (see below What the nonmedicinal ingredients are).
- you have moderate or severe liver disease.

What the medicinal ingredient is:

Roflumilast

What the nonmedicinal ingredients are:

Hypromellose, yellow iron oxide, lactose monohydrate, macrogol, maize starch, magnesium stearate, povidone and titanium dioxide

What dosage forms it comes in:

Film-coated tablets 500 mcg

The tablets are yellow and D-shaped. They are marked with a 'D' on one side.

WARNINGS AND PRECAUTIONS

BEFORE you use DAXAS talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant. Female patients who can get pregnant should use effective methods of birth control while receiving DAXAS.
- you are breast-feeding.
- you have liver disease.
- you have a history of depression linked to suicidal thoughts or behaviour.
- you are taking other medicines at the same time.
- you are under 18 years of age.
- you have a fast and/or irregular heart beat or pulse.

Take DAXAS only once a day, but be sure to take it every day.

You should immediately inform your doctor if you start to have any suicidal thoughts.

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

DAXAS is not recommended for use in patients under 18 years of age.

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

You must take DAXAS as add-on therapy to a daily bronchodilator treatment. Always follow your doctor's orders.

DAXAS is not recommended for patients having severe immunological diseases (such as HIV infection, multiple sclerosis, lupus erythematosus, progressive multifocal leukoencephalopathy, and others), severe acute infectious diseases (such as tuberculosis, or acute hepatitis), cancer (except basal-cell carcinoma, a slow-growing type of skin cancer), or severe impairment of heart function. You should talk to your doctor, if you are diagnosed with any of these diseases.

Severe allergic reactions can occur when you use DAXAS. In the rare case of severe allergic reaction, stop taking DAXAS and contact your doctor immediately, or go immediately to the emergency department in the nearest hospital. Take your medication and this leaflet with you to provide full information for your proper treatment.

INTERACTIONS WITH THIS MEDICATION

DAXAS may be taken simultaneously with other medicines used in the treatment of COPD such as inhaled bronchodilators, inhaled combination bronchodilator/corticosteroids and short-term oral corticosteroids. DAXAS works in addition to your bronchodilator medications. It works in a different way to provide additional improvement to your breathing ability and increased protection against exacerbations. Do not stop taking any of your breathing medicines or reduce their dose unless advised by your doctor.

Please let your doctor know before you start to take DAXAS if you already take medicine containing erythromycin, ketoconazole, fluvoxamine, enoxacin, cimetidine or take medicine used for treatment of immunological diseases, such as methotrexate, azathioprine, infliximab, etanercept, or oral corticosteroids to be taken long-term.

The effect of DAXAS 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 before you start to take DAXAS.

To look after you properly, it is important for your doctor to know about all medications you are taking, including those for your COPD. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including prescription medicines, medicines obtained without a prescription and natural health products.

PROPER USE OF THIS MEDICATION

Usual dose:

Always take DAXAS exactly as your doctor has told you. You should check with your doctor or pharmacist if you have any questions about how to take DAXAS.

- The usual dose is one 500 microgram tablet taken orally once daily. Do not take more tablets than your doctor has recommended.
- 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 cannot see or feel the inflammation that is occurring deep inside your lungs that DAXAS works to reduce. This is why it is important to continue taking DAXAS for as long as prescribed by your doctor, even if you have no symptoms or feel no immediate benefit from taking DAXAS. This will help to maintain control of your lung function and help protect you from exacerbations.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take a tablet at the usual time, take the tablet as soon as you remember. If on one day you have forgotten to take a tablet of DAXAS, 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 have any further questions on the use of this product, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like most prescription medicines, DAXAS can cause some side effects including nausea, dizziness, tremor and abdominal pain. Patients who experienced these side effects found they mainly occurred within the first weeks of therapy and resolved on continued treatment. Tell your doctor or pharmacist if any of these side effects become bothersome to you or persist (do not go away after the first few weeks of treatment).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical assistance
		Only if severe	In all cases	
Very common	Diarrhea	X		
Common	Anxiety		X	
	Depressive mood		X	
	Headache	X		
	Irregular heart beat		X	
	Sleeplessness	X		
	Weight decrease	X		
Uncommon	Allergic reactions, symptoms include: difficulty swallowing or breathing, rash, hives, swelling of the face, lips, or throat.			X
Rare	Nervousness	X		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical assistance
	Only if severe	In all cases	
Suicidal thinking and behaviour		X	

This is not a complete list of side effects. For any unexpected effects while taking DAXAS, contact your doctor or pharmacist.

HOW TO STORE IT

Store DAXAS between 15-30°C.

Keep out of the reach and sight of children.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Questions or concerns: 1-800-668-6000.

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