

PART III: CONSUMER INFORMATION

Pr **REVATIO***
(sildenafil tablets)
20 mg sildenafil as (sildenafil citrate)

(sildenafil solution for injection)
0.8 mg/mL sildenafil as (sildenafil citrate)

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

ABOUT THIS MEDICATION

What the medication is used for:

REVATIO (sildenafil citrate) is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels between the heart and the lungs).

REVATIO improves the ability to exercise. If you are already on a stable dose of epoprostenol (FLOLAN®) it may also slow down the worsening of your physical condition and symptoms of pulmonary hypertension.

With PAH, the blood pressure in your lungs is too high. Your heart has to work hard to pump blood into your lungs.

What it does:

REVATIO belongs to a group of medicines called phosphodiesterase type 5 inhibitors. REVATIO brings down pulmonary (lung) blood pressure by widening these vessels.

When it should not be used:

You should **not take REVATIO** if you:

- have ever had an allergic reaction to REVATIO or any medicines containing sildenafil citrate, or any of the ingredients of the drug (see "**What the non-medical ingredients are**"). An allergic reaction can be a rash, itching, a swollen face, swollen lips or shortness of breath. Please notify your doctor if this ever happens to you.
- are taking any medicines that contain nitrates in any form (oral, sublingual [under the tongue], skin patch or by inhalation. Nitrates are found in many prescriptions that are used to treat angina (chest pain due to heart disease) such as:
 - nitroglycerin (sprays, ointments, skin patches or pastes, and tablets that are swallowed or dissolved in the mouth)
 - isosorbide mononitrate and isosorbide dinitrate (tablets that are swallowed, chewed, or dissolved in the mouth)

If you are not sure if any of your medicines contain nitrates, or if you do not understand what nitrates are, ask your doctor or pharmacist. If you take **REVATIO** with

any nitrate-containing medicine or any nitrate, your blood pressure could suddenly drop to a life-threatening level. You could get dizzy, faint, or even have a heart attack or stroke.

What the medicinal ingredient is:

Sildenafil citrate

What the nonmedicinal ingredients are:

Tablets:, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Film coat: hypromellose, lactose, titanium dioxide (E-171), triacetin.

Intravenous: glucose and water for injection

What dosage forms it comes in:

REVATIO film-coated tablets contain 20 mg sildenafil (as sildenafil citrate) and are white and round in shape. The tablets are marked with "PFIZER" on one side and "RVT 20" on the other. The tablets are provided in blister packs containing 90 tablets (15 tablets per blister strip).

REVATIO solution for injection contains 0.8 mg/ml sildenafil as sildenafil citrate. It is provided in a 20 ml vial that contains 10 mg (12.5 mL) of sildenafil (as sildenafil citrate). Do not administer more than 12.5 ml and dispose of all the remainder after use. Each dose requires a new vial.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Before taking REVATIO, talk to your doctor or pharmacist if you:

- **have certain medical conditions such as heart or blood vessel diseases**
- **have ever had temporary, decrease, or permanent loss of vision in one or both eyes including a condition called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION).**

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

- have heart problems (irregular heart beats, angina, chest pain, or had a heart attack)
- have high or low blood pressure
- have kidney problems
- have liver problems
- have blood problems, including sickle cell anemia or leukemia
- have a deformed penis, Peyronie's disease, or ever had an erection that lasted more than 4 hours
- have stomach ulcers or any types of bleeding problems
- have a rare inherited eye disease called retinitis pigmentosa
- are taking an alpha blocker (a drug used to treat prostate problems or high blood pressure)
- are taking nitrates

- are taking any other medicines

Rare but serious skin reactions of Stevens-Johnson’s Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Erythema Multiforme (EM) have been reported during the post-marketing period (See Side Effects and What To Do About Them).

Pregnancy / Breast Feeding:

If you are pregnant, or think you might be pregnant, or are breast feeding, ask your doctor or pharmacist for advice before taking REVATIO.

Driving and using machines:

A small percentage of patients experience visual effects (e.g. impairment of colour discrimination, increased perception to light, blurred vision). If this happens to you, do not operate a motor vehicle or any heavy machinery until the adverse effects disappear.

unsure. The recommended oral dose is 20 mg three times a day (taken 6 to 8 hours apart) swallowed with or without food. REVATIO* solution for injection is for the continuous treatment of patients with PAH who are currently prescribed REVATIO® tablets and who are temporarily unable to take oral medication

For those patients, the recommended intravenous dose is 10 mg (corresponding to 12.5 ml) three times a day administered as an intravenous bolus injection administered by your doctor who will tell you when to resume to the tablets. Each dose requires a new vial.

If you have the impression that the effect of REVATIO is too strong or too weak, talk to your doctor or pharmacist.

Overdose:

You should not take more tablets than your doctor tells you. If you take more tablets than you have been told to take contact your doctor.

In case of accidental drug overdose, contact a health care practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take REVATIO, take a dose as soon as you remember, then continue to take it at the usual times. Do not take a double dose to make up for forgotten doses.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

Use of organic nitrates in any form is absolutely contraindicated (see **When it should not be used**)

Drugs that may interact with REVATIO include:

- Alpha-Blockers, a drug used to treat prostate problems or high blood pressure;
- Bosentan therapy for pulmonary arterial hypertension. Ask your doctor or pharmacist for advice before taking REVATIO, as your dose may need to be adjusted.
- Ketoconazole or itraconazole to treat fungal infections. You should not take REVATIO if you are taking these drugs.
- REVATIO may cause a serious increase in the effects of any medicines that contain nitrates in any form (oral, sublingual [under the tongue], skin patch or by inhalation. Nitrates are found in many prescriptions that are used to treat angina (chest pain due to heart disease) (also see Section “When it should not be used”). You should not take REVATIO if you are taking these medicines.
- Ritonavir or certain drugs for the treatment of HIV. You should talk to your doctor or pharmacist if you have prescribed these drugs.
- Cimetidine (a drug generally used to treat duodenal or gastric problems)
- Erythromycin (a drug used to treat bacterial infections)

Grapefruit juice may affect REVATIO blood levels.

If you are unsure about the medications you are taking, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, **REVATIO** can cause some side effects.

The most common side effects are headache, facial flushing, indigestion, back pain, diarrhoea, nausea and limb pain. The less commonly reported side effect is sudden decrease or loss of hearing.

Other side effects you might notice: flu-like symptoms, difficulty sleeping, effects on vision, cough, nosebleed, muscle aches, increased temperature or transient global amnesia (temporary memory loss).

Reports of serious skin reactions characterized by rash, blisters, peeling skin and pain, which require immediate medical attention, have also occurred rarely. You should stop taking REVATIO and consult your doctor if you experience such reactions.

If you notice any side effects not mentioned in this leaflet, or any of the above-mentioned effects persist or become bothersome, please inform your doctor or pharmacist.

PROPER USE OF THIS MEDICATION

Usual dose:

Always take REVATIO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are

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 call your doctor or pharmacist
	Only if severe	In all cases	
<u>Common</u>			
headache	✓		
facial flushing	✓		
indigestion	✓		
back pain	✓		
diarrhoea	✓		
nausea	✓		
limb pain	✓		
<u>Less Common</u>			
effect on hearing (sudden decrease or loss of hearing)		✓	
effects on vision (decreased eyesight or loss of vision in one or both eyes)		✓	
<u>Other Side Effects</u>			
flu-like symptoms	✓		
difficulty sleeping	✓		
muscle aches	✓		
cough		✓	
nosebleed		✓	
increased temperature		✓	
shortness of breath		✓	
transient global amnesia (temporary memory loss).		✓	
Serious skin reactions characterized by rash, blisters, peeling skin and pains.			✓

Loss of Vision

REVATIO belongs to a group of medicine called phosphodiesterase type 5 inhibitors. In rare cases men using such medicines for erectile dysfunction have reported a sudden decrease or loss of vision in one or both eyes. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, call your doctor immediately for advice.

pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C, in the original package. Do not take REVATIO after the expiry date shown on the package. Keep out of reach and sight of children.

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 0701C
Ottawa, ON K1A 0K9

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

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

MORE INFORMATION

Please note that the information contained in the enclosed pamphlet is general. Your doctor and pharmacist are your primary sources of information about your health and the medicine you take. Consult with you doctor or pharmacist if you have questions about your health, any medication you take or the information we are providing you.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.Pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001

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