

PART III: CONSUMER INFORMATION

PrREVATIO®
sildenafil tablets, Mfr. Std.
20 mg sildenafil as (sildenafil citrate)

sildenafil injection BP
0.8 mg/mL sildenafil as (sildenafil citrate)

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE.

Read this carefully before you start taking REVATIO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about REVATIO.

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) in adults (18 years of age or older).

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 pulmonary arterial hypertension, the blood pressure in your lungs is too high. Your heart has to work hard to pump blood into your lungs.

If you are currently prescribed oral REVATIO and are temporarily unable to take oral medication, REVATIO is also available as an injectable solution.

REVATIO is not indicated for use in children less than 18 years of age.

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:

Do not use 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 are the ingredients in REVATIO?"). 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.

- have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
- take drugs like ketoconazole (Nizoral®), itraconazole (Sporanox®), ritonavir (Kaletra®)
- have pulmonary hypertension secondary to sickle cell anaemia (abnormality of the red blood cells)
- have severe liver disease
- have a recent history of stroke or heart attack or life-threatening arrhythmia (a heart rhythm disorder)
- have a coronary artery disease (heart vessels disease) causing unstable angina (chest pain)
- have severe hypotension (low blood pressure) when you start taking REVATIO
- take guanylate cyclase stimulators, such as riociguat (Adempas®)

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 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 high blood pressure in your lung arteries (pulmonary veno-occlusive disease)
- have 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 you:

- have heart problems (irregular heartbeats, angina, chest pain, or had a heart attack or stroke)
- 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, abnormal curvature of the penis), or ever had an erection lasting more than 4 hours
- have stomach ulcers or any types of bleeding problems
- have an eye disease called retinitis pigmentosa
- are taking an alpha blocker (a drug used to treat high blood pressure or prostate problems)
- are pregnant or breastfeeding
- are taking bosentan therapy for pulmonary arterial hypertension.
- are taking products such as Viagra (sildenafil), Cialis, Levitra, Adcirca and Staxyn.
- are taking any other medicines

Driving and using machines:

A small percentage of patients experience dizziness or altered vision. You should be aware of how you might be affected by REVATIO before driving or operating machinery.

INTERACTIONS WITH THIS MEDICATION**Serious Drug Interactions**

- Use of organic nitrates in any form is absolutely contraindicated (see Do not use REVATIO if:)
- Use of products such as Viagra (sildenafil), Cialis, Levitra, Adcirca and Staxyn, and
- Use of other vasodilators, a class of drugs that open (dilate) the blood vessels (see **WARNINGS AND PRECAUTIONS**)

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Drugs that may interact with REVATIO include:

- Alpha-Blockers (e.g. doxazosin), drugs used to treat high blood pressure or prostate problems
- Beta-Blockers and amlodipine, drugs used to treat high blood pressure
- Bosentan therapy for pulmonary arterial hypertension.
- Calcium channel blockers (e.g. amlodipine, verapamil) drugs used to treat high blood pressure, angina and abnormal heart rhythms
- Ketoconazole or itraconazole to treat fungal infections.
- 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”).
- Ritonavir and saquinavir or other drugs used for the treatment of HIV.
- Cimetidine (a drug generally used to treat duodenal or gastric problems)
- Erythromycin, clarithromycin and telithromycin (drugs used to treat bacterial infections)
- Nefazodone (a drug used to treat depression)

Grapefruit juice may affect REVATIO blood levels. You should avoid taking REVATIO with grapefruit juice.

Alcohol can react with REVATIO. It may increase the heart rate, decrease standing blood pressure, or cause dizziness, and headache. You should avoid consuming alcohol while taking REVATIO.

St-Johns’s Wort may affect REVATIO blood levels. You should advise your doctor if you are taking St-Johns’s wort.

If you are unsure about the medications you are taking, ask 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 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 is for the continuous treatment of patients with pulmonary arterial hypertension 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.

REVATIO is not indicated for use in children less than 18 years of age.

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.

If you think you have taken too much REVATIO, contact your health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of REVATIO, take it as soon as you remember, then continue with your next scheduled dose. Do not take two doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

These are not all the possible side effects you may feel when taking REVATIO. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

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 pain in extremity.

Other side effects you might notice: flu-like symptoms, difficulty sleeping, muscle aches.

If any of these side effects is severe, talk with your doctor or pharmacist.

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.

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

Frequency	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Less Common	Effect on hearing (sudden decrease or loss of hearing)		✓	
	Blurred vision		✓	
	Impaired vision (decreased eyesight or loss of vision in one or both eyes)			✓
Unknown	Cough		✓	
	Nosebleed		✓	

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Frequency	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	Fever		✓	
	Shortness of breath		✓	
	Seizure, seizure recurrence			✓
	Transient global amnesia (temporary memory loss).		✓	
	Serious skin reactions characterized by rash, blisters, peeling skin and pains.			✓
	Erection lasting more than 4 hours (Priapism)			✓
	<i>Noted in patients taking sildenafil citrate for erectile dysfunction:</i> Heart problems symptoms like heart attack (Myocardial infarction), chest pain (unstable angina), irregular heart beat (ventricular arrhythmia), bleeding in the brain (cerebrovascular haemorrhage)			✓
	<i>Noted in patients taking sildenafil citrate for erectile dysfunction:</i> Transient ischaemic attack symptoms like temporary loss of vision, difficulty speaking, weakness on one side of the body, numbness or tingling usually on one side of the body, dizziness, lack of coordination or poor balance.			✓

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

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	<p><i>Noted in patients taking sildenafil citrate for erectile dysfunction:</i></p> <p>Pulmonary Haemorrhage (acute bleeding from the lung) symptoms like oozing of bloody fluid from the nose and respiratory tract, accompanied by rapid worsening of patient respiration, cyanosis and in severe cases, shock)</p>			✓

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. If you experience sudden decrease or loss of vision, you should stop taking REVATIO and call your doctor immediately for advice.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional

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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.viatris.ca> or by contacting the sponsor, BGP Pharma ULC, at: 1-844-596-9526

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