

Sildenafil (Revatio)

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Sildenafil is used to treat pulmonary arterial hypertension, also known as Group 1 pulmonary hypertension. The treatment aims to improve patients' ability to exercise and delay disease progression.

Sildenafil is a phosphodiesterase 5 inhibitor. Phosphodiesterase, an enzyme produced in the lungs and other parts of the body, breaks down a substance called cyclic guanosine monophosphate. Cyclic guanosine monophosphate relaxes and widens arteries. Sildenafil decreases the enzyme's activity so more cGMP is available to relax or widen the arteries. When the arteries are widened, it's easier for the heart to pump blood through the lungs, reducing blood pressure in the lungs. As the heart's ability to pump blood through the lungs increases, it improves a person's ability to exercise.

The Food and Drug Administration approved Revatio in 2005 to treat PAH. While Viagra is an FDA-approved form of sildenafil, it's not used to treat PAH. Viagra treats erectile dysfunction.

Women and men with PAH can use sildenafil. No differences in side effects have been reported among genders. Studies haven't shown any effect on sexual function in women who have taken sildenafil.

Dosage

Revatio is a round, white 20 mg pill, which distinguishes it from Viagra, a blue diamond-shaped pill.

The recommended, FDA-approved dose for sildenafil as Revatio is 20 mg three times a day. Patients have received up to 80 mg three times a day in trials and clinical practice.

Take each dose four to six hours apart, with or without food.

The injected form of Revatio generally is available only in hospitals. It's administered three times a day, through single-use 10 mg (12.5 mL) doses.

Obtaining sildenafil

Doctors must prescribe sildenafil, and insurance approval generally is required before starting therapy. Depending on your insurance, you might fill your prescription at a retail pharmacy or through specialty pharmacies such as Accredo, Aetna, Alliance Rx Walgreens Prime, Axiom, BriovaRx, Cigna, CVS/Caremark specialty, Humana and Kaiser Permanente.

Insurance

Most health insurance plans will pay part of the medication cost. However, some plans have high out-of-pocket costs. Ask your insurance company for information about specific copay or out-of-pocket costs. Depending on your



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insurance plan, you might be eligible for assistance from the company that manufactures the drug or copay assistance from a non-profit charitable organization. [See the list](#) or call 301-565-3004.

Common side effects

Sildenafil is generally well tolerated. The most common side effects are:

- Nose bleeds.
- Upset stomach and heartburn.
- Difficulty sleeping.
- Skin reddening.
- Worsening shortness of breath.
- Nasal congestion.

Other side effects include fluid retention, nausea and diarrhea, arm or leg pain, temporary muscle aches, fever and numbness.

Potential side effects

Blood pressure throughout the body can decrease because sildenafil relaxes arteries throughout the body. Patients with low blood pressure (less than 90/50 mmHg) should use sildenafil with caution. People with dehydration, left-heart diseases and certain abnormalities of the body's nervous system function also should use this with caution.

Taking certain medications, such as nitrates, nitric oxide donors or alpha blockers, with sildenafil is a dangerous risk factor. Taking nitrates with sildenafil can cause blood pressure to drop significantly and could result in loss of consciousness or even death. Avoid taking these medications before starting sildenafil.

Prolonged erection (greater than four hours) in male patients is rare but serious. If you experience prolonged erection, go to an emergency room or contact your doctor immediately.

Sudden loss of vision in one or both eyes has occurred in patients on phosphodiesterase 5 inhibitors. Sudden vision loss can indicate serious dysfunction of the optic nerve and needs immediate medical attention.

If sudden hearing loss accompanied by dizziness and/or ear ringing occurs, seek prompt medical attention.

Monitoring for side effects

No regular bloodwork for side effects is required. Your doctor might ask you to monitor your blood pressure regularly, particularly during your first few days taking the drug or when your dose increases. Blood pressure monitoring isn't necessary for most patients.



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If you experience any symptoms mentioned in the previous section, promptly notify your physician.

Considerations for special populations

Pregnancy and breastfeeding: Sildenafil hasn't shown harm to fetuses in animal studies. However, birth effects haven't been studied in pregnant or nursing women. There are no adequate and well-controlled human studies. In clinical practice, sildenafil is commonly used for pregnant and lactating women with severe PAH, as the risk of untreated or undertreated PAH is higher than the risk of adverse effects from sildenafil.

Children: Clinical trials of sildenafil for pediatric PAH patients have been small and as part of studies with a wide range of ages and diseases. Generally, sildenafil seems safe and effective for pediatric patients. The treatment algorithm from the sixth World Symposium on Pulmonary Hypertension recommended PDE5 inhibitors for pediatric patients.

Mild to moderate liver disease: Doesn't require a dose adjustment. Severe liver disease hasn't been studied.

Kidney disease: Dose adjustments aren't required.

Sickle cell: Patients with sickle cell disease and PH can develop a serious condition known as vaso-occlusive crisis. Sildenafil's effectiveness for PH related to sickle cell anemia hasn't been established.

Human immunodeficiency virus (HIV or AIDS): If you take antiretroviral agents, consult you pharmacist before taking phosphodiesterase inhibitors such as sildenafil since they can dramatically impair the efficacy of some antiretrovirals.

Other rare diseases associated with PH: Sildenafil isn't recommended for people with pulmonary veno-occlusive disease and pulmonary capillary hemangiomatosis.

Drug interactions (See package insert for full details)

Sildenafil shouldn't be used in combination with nitrates or nitric oxide donors as an unsafe drop in systemic blood pressure may occur.

Use caution when drinking alcoholic beverages or taking anti-hypertension or blood pressure-lowering medications.

Sildenafil is broken down predominantly by an enzyme called CYP3A in the liver. Significant interactions can occur with medications that affect this enzyme pathway.

Simultaneous use of bosentan and sildenafil can increase bosentan in blood and decrease sildenafil levels. It's not known whether those changes are clinically significant.

Using sildenafil with epoprostenol can reduce sildenafil levels in the blood.

Using sildenafil with beta blockers (a heart or blood pressure medicine) can increase sildenafil levels.



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Allergies

Although allergies to sildenafil are possible, they aren't likely. Any medication can cause side effects or sensitivities. Check with your doctor if you develop a rash or throat tightening.

Other considerations

Rare case of blindness have been reported for PDE5 inhibitors, including sildenafil. This type of blindness, called non-arteritic anterior ischemic optic neuropathy, can be permanent. It isn't clear whether the blindness is related to the drug or underlying cardiovascular diseases that increase the risk for this type of blindness, even without sildenafil use.

No research exists to determine whether sildenafil is beneficial or safe for people with retinitis pigmentosa. Sildenafil isn't recommended for people with that condition.

Seek immediate medical attention if you suddenly lose your vision.



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