

PATIENT INFORMATION

REVATIO® (re-VAH-tee-oh) (sildenafil) tablets

Read the Patient Information that comes with REVATIO before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about REVATIO, ask your doctor or pharmacist.

What is the most important information I should know about REVATIO (sildenafil)?

Never take REVATIO with any nitrate medicines. Your blood pressure could drop quickly. It could fall to an unsafe level. Nitrate medicines include:

Medicines that treat chest pain (angina)

Nitroglycerin in any form

Isosorbide mononitrate or dinitrate

Street drugs called “poppers” (amyl nitrate or nitrite)

Ask your doctor or pharmacist if you are not sure if you are taking a nitrate medicine.

What is REVATIO (sildenafil)?

REVATIO is a prescription medicine used to treat pulmonary arterial hypertension (PAH). With PAH, the blood pressure in your lungs is too high. Your heart has to work hard to pump blood into your lungs.

REVATIO improves the ability to exercise and can help lessen symptoms and slow down worsening changes in your physical condition.

REVATIO has not been studied

- in children under 18 years old
- in patients who are also taking a medicine called bosentan (Tracleer®)

REVATIO contains the same medicine as VIAGRA® (sildenafil), which is used to treat erectile dysfunction (impotence). Do not take REVATIO with VIAGRA or other PDE5 inhibitors.

Who should not take REVATIO (sildenafil)?

Do not take REVATIO if you

- take nitrate medicines. See “What is the most important information I should know about REVATIO?”
- are allergic to sildenafil or any other ingredient in REVATIO. See “What are the ingredients in REVATIO?” at the end of this leaflet.

What should I tell my doctor before taking REVATIO (sildenafil)?

Tell your doctor about all of your medical conditions, including if you

- have had a heart attack, stroke, or irregular heartbeats in the last 6 months
- have chest pain (angina)
- have a disease called pulmonary veno-occlusive disease (PVOD)

- have high or low blood pressure or blood circulation problems
- have an eye problem called retinitis pigmentosa
- have or had loss of sight in one or both eyes
- have liver or kidney problems
- have any problem with the shape of your penis
- lose a large amount of body fluids (dehydration). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot or don't drink enough liquids.
- have any blood cell problems such as cancer of blood cells or bone marrow or sickle cell anemia
- have a stomach ulcer or any bleeding problems
- are pregnant or planning to become pregnant. It is not known if REVATIO could harm your unborn baby.
- are breastfeeding. It is not known if REVATIO passes into your breast milk or if it could harm your baby.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. REVATIO and certain other medicines can cause side effects if you take them together. The doses of some of your medicines may need to be adjusted while you take REVATIO.

Especially tell your doctor if you

- Take nitrate medicines. See “**What is the most important information I should know about REVATIO?**”
- Take ritonavir (Norvir[®]) or other medicines used to treat HIV infection
- Use ketoconazole (Nizoral[®])

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take REVATIO (sildenafil)?

- Take REVATIO exactly as your doctor tells you.
- REVATIO is a tablet you take by mouth. Take a REVATIO tablet 3 times a day about 4 to 6 hours apart.
- Take REVATIO at the same times every day, with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, skip the missed dose, and take your next dose at the regular time.
- Do not take more than one dose of REVATIO at a time.
- Do not change your dose or stop taking REVATIO on your own. Talk to your doctor first.
- **If you take too much REVATIO, call your doctor or poison control center, or go to an emergency room.**

What are the possible side effects of REVATIO (sildenafil)?

The following side effects were reported in patients taking REVATIO. Some of these were serious.

- **low blood pressure.** Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy.

- **more shortness of breath than usual.** Tell your doctor if you get more short of breath after you start REVATIO. More shortness of breath than usual may be due to your underlying medical condition.

The following side effects were reported rarely in patients taking sildenafil:

- **decreased eyesight or loss of sight in one or both eyes (NAION).** If you notice a sudden decrease or loss of eyesight, talk to your doctor right away. It is not possible to determine if these events are related to oral medicines for the treatment of erectile dysfunction, including sildenafil, or to other medical problems, or combination of these factors.
- **sudden decrease or loss of hearing.** If you notice a sudden decrease or loss of hearing, talk to your doctor right away. It is not possible to determine whether these events are related directly to this class of oral medicines, including sildenafil, or to other diseases or medications, to other factors, or to a combination of factors.
- **heart attack, stroke, irregular heartbeats, and death.** Most of these happened in men who already had heart problems.
- **erections that last several hours.** Tell your doctor right away if you have an erection that lasts more than 4 hours.

The most common side effects are nosebleed, headache, upset stomach, getting red or hot in the face (flushing), and trouble sleeping.

Tell your doctor if you have any side effect that bothers you or doesn't go away.

These are not all the possible side effects of REVATIO. For more information, ask your doctor or pharmacist.

How should I store REVATIO (sildenafil)?

- Store REVATIO at room temperature, 59-86°F (15-30°C).
- **Keep REVATIO and all medicines away from children.**

General information about REVATIO (sildenafil)

Medicines are sometimes prescribed for conditions that are not in the patient leaflet. Do not use REVATIO for a condition for which it was not prescribed. Do not give REVATIO to other people, even if they have the same symptoms you have. It could harm them.

This patient leaflet summarizes the most important information about REVATIO. If you would like more information about REVATIO:

- Ask your doctor or pharmacist for information about REVATIO that is written for health professionals.
- Go to www.REVATIO.com or call 1-800-879-3477.

What are the ingredients in REVATIO (sildenafil)?

Active ingredients: sildenafil citrate

Inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, lactose monohydrate, and triacetin

Rx only



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