

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Revatio.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with Revatio against the benefits they expect it will have for you.

It should be used only under strict medical supervision.

If you have any concerns about treatment with this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Revatio is used for

This medicine is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). Revatio lowers the blood pressure by relaxing these vessels.

Revatio contains the active ingredient sildenafil (present as sildenafil citrate) which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Revatio is not for use in children under 18 years of age.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before treatment with Revatio

When Revatio must not be used

You must not use Revatio if you are taking nitrite or nitrate medications.

If you are being treated for angina (chest pain), or other heart conditions with medicines called nitrates do not use Revatio.

Nitrate medicines include glyceryl trinitrate (also called nitroglycerin).

Common tradenames for glyceryl trinitrate tablets include Anginine and Lycinate.

Common tradenames for glyceryl trinitrate patches include Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitrans.

Common tradenames for glyceryl trinitrate sprays include Nitrolingual and Glytrin.

Tradenames for glyceryl trinitrate injections include Glyceryl Trinitrate Concentrate and Glyceryl Trinitrate.

Common tradenames for other nitrate preparations include Imdur Durules, Monodur Durules, Sorbidin, Isordil, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside.

There may be other tradenames not listed here.

Do not use Revatio if you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).

GCS is a type of medicine used to treat high blood pressure in the blood vessels in the lungs caused by blood clots in the lungs (chronic thromboembolic pulmonary hypertension, CTEPH) or narrowing of the vessels that carry blood from the heart to the lungs (pulmonary arterial hypertension or PAH).

Do not use Revatio if you have

- suffered a heart attack or stroke in the last 6 months
- severe liver problems
- blood pressure that is unusually low and is not effectively treated
- an eye disease called retinitis pigmentosa
- loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION).

Do not use Revatio if you are taking

- certain medicines used to treat fungal infections including ketoconazole and itraconazole
- ritonavir, a treatment for HIV infection.

Do not use Revatio if you have an allergy to:

- sildenafil or similar medicines
- any of the ingredients listed at the end of this leaflet

An allergic reaction can include:

- hives, itching or skin rash
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing.

Do not use Revatio if the packaging is torn or shows signs of tampering.

Do not use Revatio if the expiry date on the pack has passed.

Before treatment with Revatio

Tell your doctor if:

You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

You have previously had sudden loss of eyesight in one or both eyes.

You have any of the following medical conditions:

- heart or blood vessel problems
- high blood pressure
- diabetes, especially if you also have eye problems
- leukaemia (cancer of the blood cells)
- multiple myeloma (a cancer of the bone marrow)
- any bleeding disorder such as haemophilia or problems with nose bleeds
- stomach ulcer
- a disease of the blood called sickle cell anaemia
- pulmonary veno-occlusive disease (blockage or narrow vein in the lung)
- any disease or deformity of your penis

- you are receiving any treatment for male erectile dysfunction (impotence) including Viagra which contains the same medicine, sildenafil, as Revatio. There are other tradenames for sildenafil containing medicines that are not listed here. Other medicines used to treat impotence include Cialis and Levitra
- you are receiving other treatments for your condition
- you previously experienced sudden decrease or loss of hearing.

You are pregnant or planning to become pregnant.

Revatio should not be used during pregnancy. Your doctor will discuss the risks with you.

You are breastfeeding.

You should not breastfeed while being treated with Revatio.

If you have not told your doctor or pharmacist about any of the above, tell them before you start treatment with Revatio.

Taking other medicines

Do not use Revatio if you are using nitrate medicines for angina.

Do not use Revatio if you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).

Tell your doctor if you are taking any other medicines for pulmonary arterial hypertension.

These medicines include Tracleer (bosentan), Flolan (epoprostenol) or Ventavis (Iloprost).

You may need to take different medicines or take different amounts of your medicine.

Also tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Revatio may interfere with each other. These include:

- medicines called alpha-blockers. These are used to treat high blood pressure or prostate problems
- some medicines used to treat epilepsy such as phenytoin, carbamazepine and phenobarbital
- St John's wort that may be used to treat mild anxiety
- Rifampicin used to treat leprosy or tuberculosis
- An antibiotic called erythromycin
- Saquinavir, a medicine used to treat HIV infection
- Cimetidine for stomach ulcers.

You may need to take different medicines or different amounts of your medicine. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while you are being treated with Revatio.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

Avoid drinking grapefruit juice. It may increase the level of sildenafil in your blood.

You may feel lightheaded if you drink alcohol while you are using Revatio.

Treatment with Revatio

Take Revatio tablets exactly as your doctor has prescribed.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual dose is one 20 mg tablet taken three times a day (taken 6-8 hours apart).

How to take it

Swallow the Revatio tablet whole with a full glass of water.

When to take it

Take Revatio tablets at the same times each day.

Taking Revatio tablets at the same times each day will have the best effect. It will also help you to remember when to take it.

Revatio tablets can be taken with or without food.

How long to take it

You must take Revatio tablets every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you forget to take Revatio tablets, take a dose as soon as you remember, then continue to take your tablets at the usual times.

Do not take a double dose to make up for missed tablets.

Revatio Solution for Injection

Revatio Solution for Injection is given as an injection into a vein by a doctor or trained nurse.

Your doctor will determine your dose and how long you need to be given Revatio Solution for Injection.

The usual dose of is 10 mg three times a day (given 6-8 hours apart).

Revatio Solution for Injection is given when you are unable to take Revatio tablets.

A dose of 10 mg Revatio Solution for Injection is predicted to provide an effect of sildenafil equivalent to a 20 mg oral dose.

Revatio Solution for Injection will be given to you under close medical supervision. It is unlikely that a dose would be missed.

However, tell your doctor or nurse if you think that a dose has been forgotten.

If you use too much (Overdose)

If you take or think you have been given too much, you are more likely to experience side effects.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else has received too much Revatio tablets.

Do this even if there are no signs of discomfort.

As your doctor will supervise how much Revatio injection you are given, you are unlikely to have an overdose.

While you are being treated with Revatio

Things you must do

You must stop treatment with Revatio if you have a loss of eyesight in one or both eyes, or have an erection that lasts more than 4 hours. Seek medical attention urgently.

If you are about to start taking any new medicines, especially nitrates or Adepmas (riociguat), tell your doctor and pharmacist that you are being treated with Revatio.

See "Before treatment with Revatio" for a list of common nitrate medications.

Tell any other doctors, dentists and pharmacists who are treating you that you are being treated with Revatio.

Things you must not do

Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are on Revatio.

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctor knows you are being treated with Revatio.

Do not take or use Revatio to treat any other conditions unless your doctor says so.

Do not give Revatio to anyone else, even if they have the same condition as you.

Things to be careful of

Revatio can cause dizziness and effects on vision. You should be aware of how you react to Revatio before you drive or operate machinery.

If you experience changes in vision, or dizziness, when on Revatio, you should not drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Revatio.

While Revatio helps most people it can cause some unwanted side effects in a few people. All medicines have side effects. If unwanted effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of possible side effects.

You may not get any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness
- flushing
- indigestion
- stuffy nose
- muscle aches, back or limb pain
- rash
- diarrhoea or upset stomach
- a numbness or tingling skin sensation
- breathlessness or coughing
- fever or flu like symptoms
- nose bleeds
- difficulty sleeping
- hayfever

- prolonged erection.

Rarely men have lost vision in one or both eyes sometime after taking drugs such as Viagra, Cialis or Levitra to treat impotence (known as erectile dysfunction).

If you lose sight in one or both eyes or experience changes in vision such as blurring, a blue colour to your vision or a greater awareness of light while on Revatio, seek medical attention urgently.

A small number of people have reported a loss of hearing, which may include a ringing or other persistent noise in the ears and dizziness, while being treated with Revatio. It is not known whether hearing loss is related to Revatio.

If you experience any loss of hearing, tell your doctor as soon as possible.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

After treatment with Revatio

Storage

Keep Revatio tablets where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep Revatio tablets in a cool, dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep the tablets in their pack until it is time to take them. If you take your tablets out of the pack they will not keep as well.

Revatio Solution for Injection will be stored in the pharmacy or in the hospital ward and is kept below 30°C.

Disposal

If your doctor tells you to stop taking Revatio tablets or if the medicine has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Revatio tablets are white and round in shape. The tablets are marked with "PFIZER" on one side and "RVT 20" on the other.

The tablets are available in blister packs containing 90 tablets in each box.

Revatio Solution for Injection comes as a clear, colourless solution in a glass vial.

Ingredients

Revatio tablets contain sildenafil (as citrate) equivalent to 20 mg sildenafil.

Other ingredients:

- microcrystalline cellulose
- anhydrous calcium hydrogen phosphate
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide

- lactose
- glycerol triacetate.

Revatio Solution for Injection 0.8 mg/mL contains sildenafil (as citrate) equivalent to 10 mg sildenafil in each 12.5 mL vial.

Other ingredients:

- glucose
- Water for Injections.

Supplier

Revatio is supplied in Australia by:

Viatrix Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

Australian Registration Numbers

Revatio 20 mg tablets - AUST R 119102.

Revatio 0.8 mg/mL Solution for Injection - AUST R 171474.

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