

Package leaflet: Information for the user

Revatio 0.8 mg/ml solution for injection sildenafil

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Revatio is and what it is used for
2. What you need to know before you are given Revatio
3. How Revatio is given
4. Possible side effects
5. How to store Revatio
6. Contents of the pack and other information

1. What Revatio is and what it is used for

Revatio contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

Revatio brings down blood pressure in the lungs by widening the blood vessels in the lungs.

Revatio is used to treat adults with high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension).

Revatio solution for injection is an alternative formulation of Revatio for patients who temporarily cannot take their Revatio tablets.

2. What you need to know before you are given Revatio

You should not be given Revatio

- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of chest pain (or “angina pectoris”). Revatio can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- if you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Revatio have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- if you have recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure (< 90/50 mmHg).

- if you are taking a medicine to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir (for HIV).
- if you have ever had loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and Precautions

Talk to your doctor before using Revatio if you:

- have a disease due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.
- have a severe heart problem.
- have a problem with the pumping chambers of your heart
- have high blood pressure in the blood vessels in the lungs.
- have low blood pressure at rest.
- lose a large amount of body fluids (dehydration) which can occur when you sweat a lot or do not drink enough liquids. This can happen if you are sick with a fever, vomiting, or diarrhoea.
- have a rare inherited eye disease (*retinitis pigmentosa*).
- have an abnormality of red blood cells (sickle cell anaemia), cancer of blood cells (leukaemia), cancer of bone marrow (multiple myeloma), or any disease or deformity of the penis.
- currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems with nose bleeds.
- take medicines for erectile dysfunction.

When used to treat male erectile dysfunction (ED), the following visual side effects have been reported with PDE5 inhibitors, including sildenafil at an unknown frequency; partial, sudden, temporary, or permanent decrease or loss of vision in one or both eyes.

If you experience sudden decrease or loss of vision, **stop taking Revatio and contact your doctor immediately** (see also section 4).

Prolonged and sometimes painful erections have been reported in men after taking sildenafil. If you have an erection, which lasts continuously for more than 4 hours, **stop taking Revatio and contact your doctor immediately** (see also section 4).

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems, as your dose may need to be adjusted.

Children and adolescents

Revatio should not be given to children and adolescents under the age of 18.

Other medicines and Revatio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of angina pectoris or “chest pain” (see section 2. Before you take Revatio).
- Tell your doctor or pharmacist if you are already taking riociguat.
- Therapies for pulmonary hypertension (e.g. bosentan, iloprost).
- Medicines containing St. John’s Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy).
- Blood thinning medicines (for example warfarin) although these did not result in any side effects.
- Medicines containing erythromycin, clarithromycin, telithromycin (these are antibiotics used to treat certain bacterial infections), saquinavir (for HIV) or nefazodone (for mental depression), as your dose may need to be adjusted.

- Alpha-blocker therapy (e.g. doxazosin) for the treatment of high blood pressure or prostate problems, as the combination of the two medicines may cause symptoms of low blood pressure (e.g. dizziness, lightheadedness).
- Medicines containing sacubitril/valsartan, used to treat heart failure.

Revatio with food and drink

You should not drink grapefruit juice while you are being treated with Revatio.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Revatio should not be used during pregnancy unless strictly necessary.

Revatio should not be given to women of child bearing potential unless using appropriate contraceptive methods.

Revatio passes into your breast milk at very low levels and would not be expected to harm your baby.

Driving and using machines

Revatio can cause dizziness and can affect vision. You should be aware of how you react to the medicine before you drive or use machines.

3. How Revatio is given

Revatio is given as an intravenous injection and will always be given to you by a doctor or a nurse. Your doctor will determine the duration of your treatment and how much Revatio intravenous injection you will receive each day and will monitor your response and condition. The usual dose is 10 mg (corresponding to 12.5 ml) three times a day.

A Revatio intravenous injection will be given to you instead of your Revatio tablets.

If you receive more Revatio than you should

If you are concerned that you may have been given too much Revatio, tell your doctor or nurse immediately. Taking more Revatio than you should may increase the risk of known side effects.

If you miss a dose of Revatio

As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However tell your doctor or pharmacist if you think that a dose has been forgotten.

A double dose should not be given to make up for a forgotten dose.

If you stop use of Revatio

Suddenly stopping your treatment with Revatio may lead to your symptoms getting worse. Your doctor may reduce the dose over a few days before stopping completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Revatio can cause side effects, although not everybody gets them.

If you experience any of the following side effects you should stop taking Revatio and contact a doctor immediately (see also section 2):

- if you experience sudden decrease or loss of vision (frequency not known)
- if you have an erection, which lasts continuously for more than 4 hours. Prolonged and sometimes painful erections have been reported in men after taking sildenafil (frequency not known).

Adults

Side effects reported in a clinical trial with intravenous Revatio were similar to those reported in clinical trials with Revatio tablets. In clinical trials the side effects reported commonly (may affect up to 1 in 10 people) were facial flushing, headache, low blood pressure and nausea.

In clinical trials side effects reported commonly (may affect up to 1 in 10 people) by patients with pulmonary arterial hypertension were facial flushing and nausea.

In clinical trials with Revatio tablets side effects reported very commonly (may affect more than 1 in 10 people) were headache, facial flushing, indigestion, diarrhoea and pain in the arms or legs.

Side effects reported commonly (may affect up to 1 in 10 people) included: infection under the skin, flu-like symptoms, inflammation of the sinuses, reduced number of red blood cells (anaemia), fluid retention, difficulty sleeping, anxiety, migraine, shaking, “pins and needles”-like sensation, burning sensation, reduced sense of touch, bleeding at the back of the eye, effects on vision, blurred vision and light sensitivity, effects on colour vision, eye irritation, bloodshot eyes /red eyes, vertigo, bronchitis, nosebleed, runny nose, cough, stuffy nose, stomach inflammation, gastroenteritis, heartburn, piles, abdominal distension, dry mouth, hair loss, redness of the skin, night sweats, muscle aches, back pain and increased body temperature.

Side effects reported uncommonly (may affect up to 1 in 100 people) included: reduced sharpness of vision, double vision, abnormal sensation in the eye, penile bleeding, presence of blood in semen and/or urine, and breast enlargement in men.

Skin rash and sudden decrease or loss of hearing and decreased blood pressure have also been reported at an unknown frequency (frequency cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Revatio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.

Revatio does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Revatio contains

- The active substance is sildenafil. Each ml of solution contains 0.8 mg of sildenafil (as citrate). Each 20 ml vial contains 10 mg sildenafil (as citrate).
- The other ingredients are glucose and water for injections.

What Revatio looks like and contents of the pack

Each pack of Revatio solution for injection contains one 20 ml clear glass vial, which is closed with a chlorobutyl rubber stopper and an aluminium seal.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Upjohn UK Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer:

Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

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