

**Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Revatio® 20 mg Film-coated tablets

Each film-coated tablet contains **sildenafil (as citrate) 20 mg**

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours. This medicine is intended for adults over 18 years old.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for treating pulmonary hypertension in patients over 18 years old.

Therapeutic group:

Inhibitors of the enzyme phosphodiesterase 5 (PDE5).

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to sildenafil or to any of the other ingredients in this medicine (see section 6).
- you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate. These medicines are usually given for relief of chest pain (angina pectoris). Revatio can cause a serious increase in the effects of these medicines.
- you are taking riociguat, a medicine used to treat pulmonary hypertension (which can be secondary to blood clots). Because PDE5 inhibitors such as Revatio have been shown to increase the hypotensive effect of this medicine. If you are taking riociguat or are not sure about it tell your doctor.
- you have recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure (<90/50 mmHg).
- you are taking medicine to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir (to treat HIV).
- 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).

Special warnings regarding use of the medicine

Before treatment with Revatio, tell your doctor if:

- you have a disease due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery
- you have a severe heart problem
- you have a problem with the pumping chambers of your heart
- you have high blood pressure in the blood vessels in the lungs
- you have low blood pressure at rest
- you 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.
- you have a rare inherited eye disease (*retinitis pigmentosa*)
- you 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
- you have an active stomach ulcer, a blood clotting disorder (such as haemophilia) or nose bleeds
- you take medicines for erectile dysfunction.

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.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines containing nitrates, or nitric oxide donors such as amyl nitrate. These medicines are often given for relief of angina pectoris or "chest pain" (see section 2).
- riociguat
- medicines to treat pulmonary hypertension (such as bosentan, iloprost)
- medicines containing St. John's wort (herbal medicinal product), rifampicin (to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy)
- blood thinning medicines (such as warfarin), although using these did not cause any side effects
- medicines containing erythromycin, clarithromycin, telithromycin (antibiotics used to treat certain bacterial infections), saquinavir (for HIV), or nefazodone (for depression), as your dose may need to be adjusted
- alpha-blocker medicines (such as doxazosin) for the treatment of hypertension or prostate problems, as the combination of the two medicines may cause symptoms resulting in the lowering of your blood pressure (for example dizziness).
- Medicines containing sacubitril/valsartan, used to treat heart failure.

Using this medicine and food

You can take this medicine with or without food.

Do not drink grapefruit juice while you are being treated with this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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.

This medicine should not be given to women of childbearing age unless using contraceptive methods.

Revatio passes into your breast milk in very small amounts so it is not expected to harm your baby.

Driving and using machines

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

Important information about some of this medicine's ingredients

Revatio contains lactose

If you have been told by a doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

Revatio contains sodium

This medicine contains less than 1 millimole sodium (23 mg) per tablet, so it is considered essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

The standard dosage is usually: one 20 mg tablet 3 times a day (every 6-8 hours).

Swallow the medicine with some water.

Do not crush/split/chew because the tablets are film-coated.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Taking a higher dose of this medicine than recommended may increase the risk of its known side effects.

If you forget to take the medicine

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember, **but never take a double dose!** Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Suddenly stopping your treatment with Revatio may lead to your symptoms getting worse. Do not stop taking your treatment unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping treatment completely.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. **If you have any further questions about using this medicine, consult your doctor or pharmacist.**

4. SIDE EFFECTS

As with any medicine, use of Revatio may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and consult your doctor immediately:

- if you experience sudden decrease or loss of vision (frequency not known). The loss/decrease of vision can be partial, sudden, temporary, or permanent and may affect one or both eyes.
- 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).

Very common side effects (may affect more than 1 in 10 users):

headaches, facial flushing, indigestion, diarrhoea, and pain in the arms or legs.

Common side effects (may affect 1-10 in 100 users):

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, tingling ("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, 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.

Uncommon side effects (may affect 1-10 in 1,000 users):

reduced sharpness of vision, double vision, abnormal sensation in the eye, bleeding from the penis, presence of blood in semen and/or urine, and breast enlargement in men.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

skin rash, sudden decrease or loss of hearing, and decreased blood pressure.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains: microcrystalline cellulose; calcium hydrogen phosphate (anhydrous); croscarmellose sodium; magnesium stearate; hypromellose; titanium dioxide; lactose monohydrate and glycerol triacetate.

What the medicine looks like and contents of the pack:

White to off-white, round film-coated tablet, imprinted with "RVT 20" on one side and "VLE" on the other.

Each pack contains 90 tablets packaged in blisters.

Manufacturer and registration holder:

Dexcel Pharma Technologies Ltd

10 Hakidma St., Yokneam Ilit 2069200, Israel

Registration number of the medicine in the Ministry of Health's

National Drug Registry:

135-61-31377

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