

# VIGOR

5mg

Tadalafil

What Vigor is and what it is used for

Vigor contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Vigor is used to treat:

**Erectile dysfunction in adult men:**

This is when a man cannot get or keep a hard, erect penis suitable for sexual activity. Vigor has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation Vigor works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. Vigor will not help you if you do not have erectile dysfunction. It is important to note that Vigor does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

**Pulmonary arterial hypertension in adults:**

It works by helping the blood vessels around your lungs relax, improving the flow of blood into your lungs. The result of this is an improved ability to do physical activity.

**What you need to know before you take Vigor Do not take Vigor if you:**

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain"). Vigor has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.
- have recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".
- 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 tadalafil, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Vigor.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor. Before taking the tablets, tell your doctor if you have:

- any heart problems other than your pulmonary hypertension
- problems with your blood pressure
- any hereditary eye disease
- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis
- a serious liver problem.
- a severe kidney problem.

It is not known if Vigor is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non- nerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking Vigor and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Tadalafil and contact your doctor immediately.

**Vigor should not be used as treatment of erectile dysfunction by women because these are health problems specific to men.**

**Children and adolescents**

Tadalafil is not intended for use by children and adolescents under the age of 18.

**Other medicines and Vigor**

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

Do not take Vigor if you are already taking nitrates.

Some medicines may be affected by Vigor or they may affect how well Vigor will work. Tell your doctor or pharmacist if you are already taking:

- bosentan (another treatment for pulmonary arterial hypertension)
- nitrates (for chest pain)
- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

**Vigor with drink and alcohol**

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Vigor will work and should be taken with caution. Talk to your doctor for further information.

**Pregnancy, breastfeeding and Fertility Pregnancy**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not take Vigor when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

**Breastfeeding**

Do not breastfeed while taking these tablets as it is not known if the medicine passes into human breast milk. Ask your doctor or pharmacist for advice before taking any medicine while pregnant or breastfeeding.

**Fertility**

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

**Driving and using machines**

Some men taking Vigor in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

**For pulmonary arterial hypertension**

Tadalafil is supplied as a 20 mg tablet. The usual dose is two 20 mg tablets taken once a day.

You should take both tablets at the same time, one after the other. If you have a mild or moderate liver or kidney problem, your doctor may advise you to take only one 20 mg tablet per day.

**If you take more Vigor than you should**

If you or anyone else takes more tablets than they should, tell your doctor or go to a hospital immediately, taking the medicine or pack with you. You may experience side effects described in section 4.

**If you forget to take Vigor**

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take Vigor more than once a day.

**If you stop taking Vigor**

**For the treatment of pulmonary arterial hypertension** do not stop taking your tablets, unless advised otherwise by your doctor.

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

**Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

**If you experience any of the following side effects stop using the medicine and seek medical help immediately:**

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapism, a prolonged and possibly painful erection after taking Vigor (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare).

**Side effects**

If you get any side effects, talk to your doctor or pharmacist.

**How to store Vigor**

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 blister or carton after EXP.

**Presentation-** Vigor 20mg Tablets packed in Alu/Alu strip of 8 Tablets and such one strips packed in a printed carton.

Tadalafil 5mg Tablets packed in Alu/Alu strip of 10 Tablets and such 3 strips packed in a printed carton.

**Manufactured for, & marketed by:**

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