

Package leaflet: Information for the patient

Tadalafil Hexal 20 mg, filmomhulde tabletten

tadalafil

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance tadalafil.

[Nationally completed name] is a treatment for pulmonary arterial hypertension in adults and in children aged 2 years and above.

It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors which work 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.

Other suitable formulations, such as an oral suspension, should be checked for their availability for administration to paediatric patients who require 20 mg and are not able to swallow tablets.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).

- are taking any form of nitrates such as amyl nitrite, used in the treatment of chest pain. [Nationally completed name] 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 ever had loss of vision – a condition described as “stroke of the eye” (non-arteritic anterior ischemic optic neuropathy - NAION).
- have had a heart attack in the last 3 months.
- have low blood pressure
- are taking riociguat. This medicine 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 [Nationally completed name], 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 [Nationally completed name].

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
- an abnormality of red blood cells (sickle cell anaemia)
- cancer of the bone marrow (multiple myeloma)
- cancer of the blood cells (leukaemia)
- any deformation of your penis, or unwanted or persistent erections lasting more than 4 hours
- a serious liver problem
- a serious kidney problem

If you experience sudden decrease or loss of vision or your vision is distorted, dimmed while you are taking [Nationally completed name] stop taking [Nationally completed name] 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, contact your doctor immediately.

Children and adolescents

[Nationally completed name] is not recommended for the treatment of pulmonary arterial hypertension in children under 2 years of age because it has not been studied in this age group.

Other medicines and [Nationally completed name]

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

Do NOT take these tablets if you are already taking nitrates.

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

- bosentan (another treatment for pulmonary arterial hypertension)
- nitrates (for chest pain)
- alpha blockers used to treat high blood pressure or prostate problems
- riociguat
- rifampicin (to treat bacterial infections)
- ketoconazole tablets (to treat fungal infections)
- ritonavir (for HIV treatment)
- tablets for erectile dysfunction (PDE5 inhibitors)

[Nationally completed name] with alcohol

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take [Nationally completed name], avoid excessive drinking (over 5 units of alcohol), since this may increase the risk of dizziness when standing up.

Pregnancy, breast-feeding and fertility

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. Do not take [Nationally completed name] when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

Do not breast-feed 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 breast-feeding.

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

Dizziness has been reported. Check carefully how you react to the medicines before driving or using any machinery.

[Nationally completed name] contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

[Nationally completed name] is supplied as a 20 mg tablet. Swallow the tablet(s) whole with a drink of water. The tablet(s) can be taken with or without food.

Pulmonary arterial hypertension in adults

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.

Pulmonary arterial hypertension in children (age 2 years and above) weighing at least 40 kg

The recommended dose is two 20 mg tablets taken once a day. Both tablets should be taken 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.

Pulmonary arterial hypertension in children (age 2 years and above) weighing less than 40 kg

The recommended dose is one 20 mg tablet taken once a day. If you have a mild or moderate liver or kidney problem, your doctor may advise you to take 10 mg once per day.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

If you take more [Nationally completed name] than you should

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

If you forget to take [Nationally completed name]

Take your dose as soon as you remember if it is within 8 hours of when you should have taken your dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking [Nationally completed name]

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.

4. 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 skin rashes (frequency common, may affect up to 1 in 10 people)
- chest pain - do not use nitrates, but seek immediate medical assistance (frequency common, may affect up to 1 in 10 people)
- priapism, a prolonged and possibly painful erection after taking tadalafil (frequency uncommon, may affect up to 1 in 100 people). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (rarely reported, may affect up to 1 in 1,000 people), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known)

The following side effects have been very commonly reported in patients taking tadalafil (may affect more than 1 in 10 people): headache, flushing, nasal and sinus congestion (blocked nose), nausea, indigestion (including abdominal pain or discomfort), muscle aches, back pain and pain in the extremity (including limb discomfort)

Other side effects have been reported:

Common (may affect up to 1 in 10 people)

- blurred vision, low blood pressure, nosebleed, vomiting, increased or abnormal uterine bleeding, swelling of the face, acid reflux, migraine, irregular heartbeat and fainting

Uncommon (may affect up to 1 in 100 people)

- seizures, passing memory loss, hives, excessive sweating, penile bleeding, presence of blood in semen and/or urine, high blood pressure, fast heart rate, sudden cardiac death and ringing in the ears

PDE5 inhibitors are also used for the treatment of erectile dysfunction in men. Some side effects have been rarely reported:

- Partial, temporary or permanent decrease or loss of vision in one or both eyes and serious allergic reaction which causes swelling of the face or throat. Sudden decrease or loss of hearing has also been reported.

Some side effects have been reported in men taking tadalafil for the treatment of erectile dysfunction. These events were not seen in clinical studies for pulmonary arterial hypertension and therefore frequency is unknown:

- swelling of the eyelids, eye pain, red eyes, heart attack and stroke

Some additional rare side effects have been reported in men taking tadalafil that were not seen in clinical trials. These include:

- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

Most but not all of those men reporting fast heart rate, irregular heartbeat, heart attack, stroke and sudden cardiac death had known heart problems before taking tadalafil. It is not possible to determine whether these events were related directly to tadalafil.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly **via the national reporting system** listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store **[Nationally completed name]**

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 carton and blister after “EXP”. The expiry date refers to the last day of that month.

This medicine 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 protect the environment.

6. Contents of the pack and other information

What **[Nationally completed name]** contains

The active substance is tadalafil.

- Each film-coated tablet contains 20 mg of tadalafil.
- The other excipients are: lactose monohydrate, sodium laurilsulfate, povidone K-12, crospovidone (Type B), sodium stearyl fumarate in the core; polyvinyl alcohol (E 1203), macrogol 3350 (E 1521), titanium dioxide (E 171), talc, iron oxide yellow (E 172) in the film-coating.

What **[Nationally completed name]** looks like and contents of the pack

Ochre to yellow, oval shaped film-coated tablet of approximately 15 x 9 mm. On one side debossed with “20”. The other side of the tablet is bi-scored. The tablet can be divided into equal halves and/or quarters.

The film-coated tablets are packed in aluminium/OPA/aluminium/PVC blisters or PVC/ACLAR/PVC-aluminium blisters or PVC/ACLAR/PVdC/PVC/aluminium blisters and inserted in a carton.

Pack sizes:

NL/H/3616/001/DC

4x1, 8x1, 12x1, 14x1, 24x1, 28x1, 36x1, 56x1, 112x1

NL/H/3617/001/DC

4x1, 8x1, 12x1, 14x1, 24x1, 28x1, 36x1, 56x1, 112x1, 120x1

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen:

Hexal AG
Industriestraße 25
83607 Holzkirchen
Duitsland

Fabrikanten:

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

TEVA PHARMA, S.L.U.
Polígono Industrial Malpica, C/C, nº4
50016, Zaragoza
Spanje

In het register ingeschreven onder:

Tadalafil Hexal 20 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 118160.

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte en het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

| | |
|-----------|--|
| Nederland | Tadalafil Hexal 20 mg, filmomhulde tabletten |
| Duitsland | TadaHEXAL PAH 20 mg Filmtabletten |
| Frankrijk | Tadalafil GNRpellicula EFG |
| Italië | Tadalafil Sandoz GmbH |

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.