

Package leaflet: Information for the patient

Tadalafil 1A Pharma 2,5 mg, filmomhulde tabletten
Tadalafil 1A Pharma 5 mg, filmomhulde tabletten
Tadalafil 1A Pharma 10 mg, filmomhulde tabletten
Tadalafil 1A Pharma 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 which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

[Nationally completed name] **2.5 mg, 5 mg, 10 mg and 20 mg** film-coated tablets is used to treat adult men with **erectile dysfunction**.

This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

[Nationally completed name] has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Following sexual stimulation [Nationally completed name] 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. [Nationally completed name] will not help you if you do not have erectile dysfunction. It is important to note that [Nationally completed name] for the treatment of erectile dysfunction 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.

[Nationally completed name] **5 mg** film-coated tablets is used to treat adult men with urinary symptoms associated with a common condition called **benign prostatic hyperplasia**.

This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. [Nationally completed name] improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. [Nationally completed name] has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

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 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”). [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 serious heart disease or recently had a heart attack within the last 90 days
- 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 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 before taking [Nationally completed name].

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.

If you are treated for benign prostatic hyperplasia with [Nationally completed name] **5 mg** film-coated tablets: since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with [Nationally completed name] for benign prostatic hyperplasia. [Nationally completed name] does not treat prostate cancer.

Before taking the tablets, tell your doctor if you have:

- 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 [Nationally completed name] 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, 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, stop taking [Nationally completed name] and contact your doctor immediately.

[Nationally completed name] is not intended for use by women.

Children and adolescents

[Nationally completed name] is not intended for use by children and adolescents under the age of 18.

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 [Nationally completed name] 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:

- 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

[Nationally completed name] with drink and alcohol

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

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 [Nationally completed name] in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

[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] tablets are for oral use in men only. Swallow the tablet whole with some water. [Nationally completed name] 20 mg tablets can be divided into equal doses. The tablets can be taken with or without food.

For the treatment of erectile dysfunction

- **Flexible-dose, on demand, using 10 mg or 20 mg film-coated tablets:**

The recommended starting dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak your doctor may increase the dose to 20 mg. [Nationally completed name] tablets are for oral use.

You may take a [Nationally completed name] tablet at least 30 minutes before sexual activity. [Nationally completed name] may still be effective up to 36 hours after taking the tablet.

[Nationally completed name] 10 mg and 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.
- **Once a day dosing, using 2.5 mg or 5 mg film-coated tablets:**

The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day. Your doctor may adjust the dose to 2.5 mg based on your response to [Nationally completed name]. This will be given as a 2.5 mg tablet.

When taken once a day [Nationally completed name] allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of [Nationally completed name] may be useful to men who anticipate having sexual activity two or more times per week.

Do not take [Nationally completed name] more than once a day.

It is important to note that [Nationally completed name] 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.

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take [Nationally completed name], avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

For the treatment of benign prostatic hyperplasia, using 5 mg film-coated tablets

The dose is one 5 mg tablet taken once a day at approximately the same time of the day.

If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day.

Do not take [Nationally completed name] more than once a day.

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

Contact your doctor. You may experience side effects described in section 4.

If you forget to take [Nationally completed name]

If you have a once a day dosing of [Nationally completed name], take your dose as soon as you remember but do not take a double dose to make up for a forgotten dose. You should not take [Nationally completed name] more than once a day.

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 rashes (frequency uncommon, may affect up to 1 in 100 people)
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon, may affect up to 1 in 100 people)
- priapism, a prolonged and possibly painful erection after taking [Nationally completed name] (frequency rare, may affect up to 1 in 1,000 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 (frequency rare, may affect up to 1 in 1,000 people), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known)

Other side effects have been reported:

Common (may affect up to 1 in 10 people)

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion

Uncommon (may affect up to 1 in 100 people)

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired

Rare (may affect up to 1 in 1,000 people)

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating

Heart attack and stroke have also been reported rarely in men taking [Nationally completed name]. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking [Nationally completed name] that were not seen in clinical studies. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

The side effect dizziness has been reported more frequently in men over 75 years of age taking [Nationally completed name]. Diarrhoea has been reported more frequently in men over 65 years of age taking 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 2.5 mg of tadalafil.
Each film-coated tablet contains 5 mg of tadalafil.
Each film-coated tablet contains 10 mg of 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

2.5 mg film-coated tablets:

Ochre to yellow, round shaped film-coated tablet of approximately 5 mm in diameter. On one side debossed with “2.5” and plain on the other side.

5 mg film-coated tablets:

Ochre to yellow, oval shaped film-coated tablet of approximately 8 x 4 mm. On one side debossed with “5” and plain on the other side.

10 mg film-coated tablets:

Ochre to yellow, oval shaped film-coated tablet of approximately 11 x 6 mm. On one side debossed with “10”. The other side of the tablet is plain.

20 mg film-coated tablets:

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/3614/001/DC

28x1 film-coated tablets.

NL/H/3614/002/DC

14x1, 28x1, 84x1 film-coated tablets.

NL/H/3614/003/DC

4x1, 12x1, 24x1, 36x1, 48x1 film-coated tablets.

NL/H/3614/004/DC

2x1, 4x1, 8x1, 12x1, 24x1, 36x1, 48x1, 56x1 film-coated tablets.

NL/H/3615/001/DC

28x1 film-coated tablets.

NL/H/3615/002/DC

14x1, 28x1, 84x1 film-coated tablets.

NL/H/3615/003/DC

4x1, 12x1, 24x1, 36x1, 48x1 film-coated tablets.

NL/H/3615/004/DC

2x1, 4x1, 5x1, 8x1, 10x1, 12x1, 24x1, 36x1, 48x1, 56x1 film-coated tablets.

NL/H/3634/001/DC

28x1 film-coated tablets.

NL/H/3634/002/DC

14x1, 28x1 film-coated tablets.

NL/H/3634/003/DC

4x1, 12x1 film-coated tablets.

NL/H/3634/004/DC

2x1, 4x1, 8x1, 12x1, 56x1 film-coated tablets.

Not all pack sizes may be marketed.

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

Vergunninghouder:

1 A Pharma GmbH
Industriestrasse 18
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 1A Pharma 2,5 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 118162.

Tadalafil 1A Pharma 5 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 118163.

Tadalafil 1A Pharma 10 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 118164.

Tadalafil 1A Pharma 20 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 118165.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Tadalafil 1A Pharma 2,5 mg, 5 mg, 10 mg, 20 mg, filmomhulde tabletten
Italië	Tadalafil Sandoz 2,5 mg, 5 mg, 10 mg, 20 mg, compresse rivestite con film

Deze bijsluiter is voor het laatst goedgekeurd in september 2023.