

Package leaflet: information for the user

Ligion 5 mg, zachte capsules
Ligion 10 mg, zachte capsules
Ligion 20 mg, zachte capsules
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. 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 Ligion is and what it is used for
2. What you need to know before you take Ligion
3. How to take Ligion
4. Possible side effects
5. How to store Ligion
6. Contents of the pack and other information

1. What Ligion is and what it is used for

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

Ligion 5 mg, 10 mg and 20 mg 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. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation Ligion 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. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that Ligion 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.

Ligion 5 mg 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. Tadalafil improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Tadalafil has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

Ligion 20 mg is used to treat 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.

2. What you need to know before you take Ligion

Do not take Ligion:

- If you are allergic to tadalafil, or any of the other ingredients of this medicine (listed in section 6).
- If you 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”). Ligion has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure, tell your doctor.
- If you have serious heart disease or recently had a heart attack within the last 90 days.
- If you recently had a stroke within the last 6 months.
- If you have low blood pressure or uncontrolled high blood pressure.
- If you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- 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 Ligion, 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 Ligion.

If you are treated for erectile dysfunction or benign prostatic hyperplasia: 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 soft capsules, tell your doctor if you have:

- 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 severe kidney problem.
- any heart problems other than your pulmonary hypertension.
- problems with your blood pressure.
- any hereditary eye disease.

If you are treated for benign prostatic hyperplasia: since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with tadalafil for benign prostatic hyperplasia. Tadalafil does not treat prostate cancer.

It is not known if Ligion 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 [Product name], stop taking Ligion 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 Ligion and contact your doctor immediately.

Ligion should not be used as treatment of erectile dysfunction or benign prostatic hyperplasia by women because these are health problems specific to men.

Children and adolescents

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

Other medicines and Ligion

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

Do not take Ligion if you are already taking nitrates.

Some medicines may be affected by Ligion or they may affect how well Ligion 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).
- protease inhibitors for treatment of AIDS or HIV infection (ritonavir).
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin (to treat bacterial infections);
- medicines such as ketoconazole tablets or itraconazole (to treat fungal infections).
- other treatments for erectile dysfunction (PDE5 inhibitors).

Ligion with drink and alcohol

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take Ligion, avoid excessive drinking (over 5 units of alcohol, blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

Grapefruit juice may affect how well Ligion will work and should be taken with caution. Talk to your doctor for further information.

Pregnancy, breastfeeding and fertility

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 tadalafil when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while taking these soft capsules 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.

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 soft capsules before driving or using machines.

Ligion contains soya-bean oil refined. If you are allergic to peanut or soya, do not use this medicinal product. It also **contains macroglycerol ricinolate** that may cause stomach upset and diarrhea.

3. How to take Ligion

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

Swallow the soft capsule whole with some water. The soft capsules can be taken with or without food.

For the treatment of erectile dysfunction

- **Flexible-dose, on demand: Ligion 10 mg and 20 mg** should be used; the recommended starting dose is one 10 mg capsule before sexual activity. However, if you have been given the dose of one 20 mg capsule is because your doctor has decided that the recommended dose of 10 mg is too weak. You may take a Ligion capsule at least 30 minutes before sexual activity.

Ligion may still be effective up to 36 hours after taking the soft capsule.

Ligion 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: Ligion 5 mg** should be used; the recommended dose is one 5 mg soft capsule 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 Ligion. This will be given as a 2.5 mg other tadalafil product. When taken once a day Ligion 5 mg 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 Ligion may be useful to men who anticipate having sexual activity two or more times per week.

It is important to note that Ligion 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.

For the treatment of benign prostatic hyperplasia

The dose is one 5 mg soft capsule 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 soft capsule taken once a day.

Do not take Ligion more than once a day.

For the treatment of pulmonary arterial hypertension

The usual dose is two 20 mg soft capsules taken once a day. You should take both soft capsules 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 20 mg per day.

If you take more Ligion than you should

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

If you forget to take Ligion

Take your dose as soon as you remember if it is within 8 hours of when you should have taken your dose, but do not take a double dose to make up for a forgotten capsule. **You should not take Ligion more than once a day.**

If you stop taking Ligion

For the treatment of pulmonary arterial hypertension do not stop taking your soft capsules, 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 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, 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 (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 and these are listed below, separated by indication:

Side effects in erectile dysfunction or benign prostatic hyperplasia

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 and 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 tadalafil. 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 tadalafil that were not seen in clinical trials. 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 tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking tadalafil.

Side effects in pulmonary arterial hypertension

Very common (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)

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.

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 (see paragraph “Side effects in erectile dysfunction and benign prostatic hyperplasia” above).

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 Ligion

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.

Do not use this medicine if you notice that the carton is damaged or shows signs of tampering.

Store in the original blister in order to protect from moisture.

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 Ligion contains

- The **active** substance is tadalafil. Each soft capsule contains 5, 10 or 20 mg of tadalafil.

- The **other ingredients** are:

Capsule filling: soya bean oil, glycerol monocaprylocaprate, macrogolglycerol ricinolate, lauroyl macrogolglycerides, poloxamers, butylhydroxyanisole.

Capsule shell: gelatin, glycerol, titanium dioxide (E171).

What Ligion looks like and contents of the pack

The 5 mg soft capsules are white/yellow, size 2, oval soft capsules. Capsule length is approximately 9.6 mm and width is approximately 6.4 mm.

The 10 mg soft capsules are white/yellow, size 5, oval soft capsules. Capsule length is approximately 12.7 mm and width is approximately 7.5 mm.

The 20 mg soft capsules are white/yellow, size 10, oval soft capsules. Capsule length is approximately 14.7 mm and width is approximately 9.3 mm.

PVC/PE/PVdC/Aluminium blisters in cartons of:

5 mg: 14, 28 and 84 soft capsules.

10 mg: 4 soft capsules.

20 mg: 2, 4, 8, 10, 12 and 56 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

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In het register ingeschreven onder:

Ligion 5 mg, zachte capsules

RVG 122915

Ligion 10 mg, zachte capsules

RVG 122916

Ligion 20 mg, zachte capsules

RVG 122917

This medicinal product is authorised in the Member States of the EEA under the following names:

Nederland	Ligion 5/10/20 mg, zachte capsules
Griekenland	LIGION

Deze bijsluiters is voor het laatst goedgekeurd in november 2023.