LIBEREZ FILM-COATED TABLET 5MG

Tadalafil 5mg

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What Liberez is used for

Liberez 5 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. Liberez has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.
- 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.

How Liberez works

Liberez contains the active ingredient tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE 5 inhibitors).

Following sexual stimulation Liberez 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. Liberez will not help you if you do not have erectile dysfunction. It is important to note that Liberez 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.

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

Before you use Liberez

-When you must not use it

Do not take Liberez if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (see section **Product Description)**.
- 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"). Liberez 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-artheritic 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 Liberez, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure, tell your doctor.

-Before you start to use it

Talk to your doctor before taking Liberez.

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.

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with Liberez for benign prostatic hyperplasia. Liberez 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 Liberez 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).

Liberez is not intended for use by women.

Children and adolescents

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

-Taking other medicines

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

Do not take Liberez if you are already taking nitrates.

Some medicines may be affected by Liberez or they may affect how well Liberez 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.

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- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

How to use Liberez

-How much to use

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

For the treatment of erectile dysfunction

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 Liberez. Do not take Liberez more than once a day.

From the treatment of benign prostatic hyperplasia

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 Liberez more than once a day.

-When to use it

Use as directed by your doctor or pharmacist. Liberez tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

-How long to use it

For the treatment of erectile dysfunction

When taken once a day Liberez 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 Liberez may be useful to men who anticipate having sexual activity two or more times a week.

For the treatment of benign prostatic hyperplasia

Continue taking Liberez for as long as your doctor recommends.

-If you forget to use it

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 Liberez more than once a day.

-If you take too much (overdose)

Contact your doctor. You may experience side effects (see section **Side Effects)**.

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

While you are using it

-Things you must do

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

-Things you must not do

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.

-Things to be careful of

Driving and using machines

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

Liberez contains lactose

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

Liberez contains sodium

This medicine contains less than 1 mmol sodium per tablet, essentially 'sodium-free'.

Liberez with drinks and alcohol

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 Liberez, avoid excessive drinking (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 Liberez 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.

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 Liberez (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).

Other side effects have been reported:

Common

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

Uncommon

- 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

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the ears, swelling of the hands, feet or ankles, and feeling tired.

Rare
- 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 Liberez. 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 Liberez. 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.

The side effect dizziness has been reported more frequently in men over 75 years of age taking Liberez. Diarrhoea has been reported more frequently in men over 65 years of age taking Liberez.
If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)).

Storage and Disposal of Liberez

-Storage
Keep out of the reach and sight 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.

Store below 30°C.

-Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like
Liberez Film- Coated Tablet 5 mg is a yellow, round shape film-coated tablet and plain on both sides.

-Ingredients
Liberez Film-Coated Tablet 5mg
-Active ingredient:
The active ingredient is tadalafil. Each tablet contains 5mg of tadalafil.

-Inactive ingredient:
Lactose Monohydrate, croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate, opadry II Yellow

-MAL number
Liberez Film-Coated Tablet 5 mg
MAL24096059AZ

Manufacturer:
InspiraPharma Sdn Bhd
(200401023395),
Lot 24 & 25, Jalan 8,
Kawasana Perusahaan Bakar Arang,
08000 Sungai Petani, Kedah Darul Aman,
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Product Registration Holder:
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