

LEBIVA ODS -20

Tadalafil Orally Disintegrating Strips 20mg

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What LEBIVA ODS-20 is used for

LEBIVA ODS-20 is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. LEBIVA ODS-20 has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

How LEBIVA ODS-20 works

LEBIVA ODS-20 contains the active ingredient tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE 5 inhibitors).

Following sexual stimulation LEBIVA ODS-20 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. LEBIVA ODS-20 will not help you if you do not have erectile dysfunction.

It is important to note that LEBIVA ODS-20 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.

Before you use LEBIVA ODS-20

- When you must not use it

Do not take LEBIVA ODS-20 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"). LEBIVA ODS-20 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 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 LEBIVA ODS-20 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 LEBIVA ODS-20.

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 LEBIVA ODS-20, 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.

LEBIVA ODS-20 is not intended for use by women.

Children and adolescents:

LEBIVA ODS-20 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 LEBIVA ODS-20 if you are already taking nitrates.

Some medicines may be affected by LEBIVA ODS-20 or they may affect how well LEBIVA ODS-20 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

How to use LEBIVA ODS-20**- 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.

The recommended starting dose is 10 or 20 mg taken before sexual activity. Your doctor will decide the suitable dose for you.

- When to use it

LEBIVA ODS-20 is an orally disintegrating strip for use in men only. The strip should be placed on tongue, let it dissolve and swallow the residue.

To be taken without food.

You may take a LEBIVA ODS-20 at least 30 minutes before sexual activity.

LEBIVA ODS-20 may still be effective up to 36 hours after taking it.

- How long to use it

Do not take LEBIVA ODS-20 more than once a day.

- If you forget to use it

LEBIVA ODS 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

- If you use 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 LEBIVA ODS-20**- Things you must do**

If you experience sudden decrease or loss of vision, stop taking LEBIVA ODS-20 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 LEBIVA ODS-20 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 LEBIVA ODS-20 in clinical studies have reported dizziness. Check carefully how you react to the medicine before driving or using machines.

LEBIVA ODS-20 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 LEBIVA ODS-20, 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 LEBIVA ODS-20 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 tadalafil (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** (seen in 1 to 10 in every 100 patients)

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

Uncommon (seen in 1 to 10 in every 1,000 patients)

- 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 (seen in 1 to 10 in every 10,000 patients)

- 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 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.

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.

- 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 npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of LEBIVA ODS-20

- 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 in the original package in order to protect from moisture. 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

LEBIVA ODS-20 is yellow colored, rectangular, opaque, non-sticky, orally disintegrating strip.

Presentation: Box of 4 films.

- Ingredients

-Active ingredient

Each orally disintegrating strip contains:

Tadalafil Ph. Eur. 20 mg

- Inactive ingredients

Hypromellose, Glycerol, Polysorbate 80, Propylene Glycol, Partly Dementholised Mint Oil (Limonene: 1.5-7.0%, Cineole: ≤1.5%, L-Menthone: 17.0-35.0%, Iso-Menthone: 5.0-13.0%, Menthyl acetate: 1.5-7.0%; Iso-pulgol: 1.0-3.0%, Menthol: 30.0-50.0%, Pulegone: ≤2.5%, Carvone: ≤2.0%, Cineole: Limonene: <1), Sodium Lauril Sulfate, Sucralose, Yellow oxide of iron

- MAL number(s)

MAL23096011ACZ

Product registration holder MEGA LIFESCIENCES SDN.

BHD.

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