TALIS 20

(Tadalafil Tablets 20mg)

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If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Talis 20 are used for

TALIS 20 contain the active ingredient tadalafil.

Tadalafil is used to treat adult men with:

- erectile dysfunction, also known as impotence, in men. This is when a man cannot get, or maintain, a hard erect penis suitable for sexual activity.

How Talis 20 work

Erectile dysfunction
Following sexual stimulation tadalafil
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 tadalafil 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.

Before you use Talis 20

When you must not use it
Do not take Talis 20:

- if you are allergic to tadalafil or any of the other ingredients of this medicine (see product description at the end of this leaflet). An allergic reaction may include skin rash, itching, swelling of the face, lips, tongue and throat or difficulty in breathing.
- if you are currently taking any nitrates or amyl nitrite (medicines used to treat chest pain).
- 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 have vision loss in one eye because of non-arteritic interior ischaemic optic neuropathy (NAION)
- if you are taking riociguat, medicine used to treat pulmonary arterial hypotension

Do not use this medicine after the expiry date printed on the pack has expired or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Talis 20, talk to your doctor or pharmacist.

Before you start to use it

Talk to your doctor before taking **Talis 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.

Tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.

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 or kidney problem.

You shall not use this medicine if you have rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Tadalafil is not intended for use by women.

Children and adolescents
Talis 20 is not intended for use by children and adolescents under the age of 18.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Do not take tadalafil if you are already taking nitrates.

Some medicines may be affected by tadalafil or they may affect how well tadalafil 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).
- ketoconazole, itraconazole (used to treat fungal infections)
- ritonavir, saquinavir (protease inhibitors for treatment of HIV infection).
- phenobarbital, phenytoin and carbamazepine (for treatment of fits and other CNS conditions).
- rifampicin, erythromycin, clarithromycin (for treatment of bacterial infection).
- other treatments for erectile dysfunction

Grapefruit juice may affect how well

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tadalafil will work and should be taken with caution. Talk to your doctor for further information.

How to use Talis 20

How much to use

Always take this medicine exactly as
your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Talis 20 are for oral use in men only.

- The recommended starting dose is 10 or 20 mg taken before sexual activity. Your doctor will decide the suitable dose for you.
- If you have liver or kidney problems, your doctor will adjust your dose accordingly.

How to take it

Talis 20 can be taken with or without food. Swallow **Talis 20** whole with a glass of water.

When to use it

You may take a tablet at least 30 minutes before sexual activity. **Talis 20** may still be effective up to 36 hours after taking the tablet.

How long to use it

Do not take **Talis 20** (tadalafil) more than once a day. Tadalafil is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

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 **Talis 20** more than once a day.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take this leaflet or **Talis 20** box with you so your doctor will know what you have taken.

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

While you are using Talis 20

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking **Talis 20.**

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take tadalafil, avoid excessive drinking since this may increase the risk of dizziness when standing up.

Things to be careful of

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

Side effects

If you experience any of the following side effects, stop using the medicine and seek medical help immediately:

Serious side effects (rare)

- allergic reactions including rashes, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing and breathing
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- chest pain (do not use nitrates but seek immediate medical assistance)
- prolonged and possibly painful erection after taking **Talis 20**, which lasts continuously for more than 4 hours you should contact a doctor immediately
- sudden loss of vision
- sudden loss of hearing which may be accompanied by ringing in the ears and dizziness
- heart attack, abnormal heartbeat
- stroke attack, fainting or seizure

Other side effects:

Common

- headache and dyspepsia (indigestion).
- flushing, back pain, muscle ache, nasal congestion

If you get any side effects, talk to your doctor or pharmacist. This includes any 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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Talis 20

Storage

Store up to 30°C, protected from light.

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

Talis 20 is Yellow colored, oval shaped, biconvex, film coated tablets plain on both the sides.

Ingredients

Active ingredients:
Tadalafil

Inactive ingredients:
Poloxamer (188) (Lutrol F 68), Hydroxy Propyl cellulose, Lactose Monohydrate, Crosspovidone, Microcrystalline cellulose, Colloidal Anhydrous Silica, Magnesium Stearate, Opadry Yellow II (Hypromellose, Lactose monohydrate, Titanium dioxide, Macrogol, Talc, Iron oxide yellow

MAL Number:

MAL20016137AZ

TALIS 20

(Tadalafil Tablets 20mg)

Manufacturer & Product Registration Holder

Manufacturer:
Sun Pharma Laboratories Limited,
6-9, EPIP, Kartholi, Bari Brahmana,
Jammu 181 133, India

Product Registration Holder:
RANBAXY (MALAYSIA) SDN. BHD.
Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah, Malaysia.

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