

# Instructions For Use

## TADALAFIL TABLETS FROM LT PHARMA, INDIA

Please read this document before using the medicine.

If you do not understand something or have doubts, consult your doctor.

### What does TADALAFIL TABLET contain?

The active ingredient is known as TADALAFIL. Each tablet contains TADALAFIL corresponding to 20mg TADALAFIL. TADALAFIL TABLET also contains other inactive substances.

### What does TADALAFIL TABLET look like?

The tablet is round, orange coloured with two deep score lines for easy splitting on one side and the words TADALAFIL and 20mg on the other.

### What is TADALAFIL TABLET?

TADALAFIL TABLET is the first of a new group of medication which allows adequate sexual stimulation, relaxes the blood vessels of the penis and helps erection. TADALAFIL TABLET does not increase sexual desire or fertility.

### Who should not take TADALAFIL TABLET?

Do not take TADALAFIL 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"). TADALAFIL has been shown to increase the effects of these drugs. If you are taking any form of nitrate or are unsure tell your doctor. If you have serious heart disease or have had a recent heart attack, if you have had a recent stroke, if you have low blood pressure or uncontrolled high blood pressure, if you are (hypersensitive) allergic to TADALAFIL or any of the other ingredients of TADALAFIL Tablet, this formulation is not for you.

### What precautions should I take before having TADALAFIL TABLET?

Inform your doctor if you have any penile illness, if you have had painful erections, if you have been diagnosed with a rare hereditary ophthalmic illness known as retinosis pigmentosa, or peptic ulcer or any problem of the blood coagulation. Also inform your doctor if you are taking any treatment for erectile dysfunction. You have sickle cell anaemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), leukaemia (cancer of the blood cells) or any deformation of your penis. You have a serious liver or kidney problem.

### What special advice should be given to aged patients?

Dosage adjustments are not required in elderly patients.

### Is there any special advice for patients with kidney or liver disease?

There is limited clinical trial data on the safety of TADALAFIL in the following groups; if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician: Patients with severe renal insufficiency and patients with severe hepatic insufficiency. TADALAFIL 10 mg has been the highest dose studied in patients with mild and moderate renal failure and in patients with end stage renal failure undergoing haemodialysis.

### Does the ability to drive vehicles or operate machines reduce by taking TADALAFIL TABLET?

As dizziness has been reported in men taking TADALAFIL in clinical studies, you should be aware of how you react to TADALAFIL before you drive or operate machinery.

### Can TADALAFIL TABLET be taken simultaneously with other medicines?

As a general rule, always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because occasionally they might interact. This is particularly important if you are treated with nitrates as you should not take TADALAFIL if you are taking these medicines. Do not take TADALAFIL with other medicines if your doctor tells you that you may not. You should not use TADALAFIL together with any other treatments for erectile dysfunction. **TADALAFIL is not intended for use by women or by children under the age of 18.** Keep the medication away from the reach of children.

### How is TADALAFIL TABLET taken?

The most convenient dose is decided by your doctor. The recommended dose of TADALAFIL is 20mg, taken prior to anticipated sexual activity. The maximum recommended dosing frequency is once per day. TADALAFIL may be taken between 30 minutes and 36 hours prior to anticipated sexual activity. Patients may initiate sexual activity at varying time points relative to dosing in order to determine their own optimal window of responsiveness. The dose may be lowered to 10mg based on individual response and tolerability. TADALAFIL may be taken without regard to food.

### Does TADALAFIL TABLET produce side effects?

Like all medicines, TADALAFIL can have side effects. These effects are normally mild to moderate in nature. The most common undesirable effects are headache and indigestion. Less commonly reported side effects are back pain, muscle aches, nasal congestion, facial flushing and dizziness. Uncommon effects are swelling of the eyelids, eye pain and red eyes. If you have any of these side effects and they are troublesome, severe, or do not go away, tell your doctor. Allergic reactions (including skin rashes) could occur. In rare instances it is possible that a prolonged and possibly painful erection may occur after taking TADALAFIL. If you have such an erection, which lasts continuously for more than 4 hours, you should contact a doctor immediately. In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

*If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. Heart attack, stroke, and irregular heart beats have been reported rarely in men taking TADALAFIL. Most, but not all of these men had known heart problems before taking this medicine. It is not possible to determine whether these events were directly related to TADALAFIL. Effects were seen in one animal species that might indicate impairment of fertility. Subsequent studies in man suggest that this effect is unlikely in humans.*

### Is there anything else specifically for men intolerant of lactose, one of the ingredients of Tadalafil?

TADALAFIL contains galactose and should not be taken by patients with rare hereditary problems of lactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

### How should TADALAFIL TABLET be stored?

Keep the TADALAFIL TABLETS in their original packing, at temperature which is below 25 degrees centigrade (77 degrees Fahrenheit).

**Do not administer this medicine after the expiry date printed on the packing.**