

# TADALIN-20

## TADALAFIL TABLETS

### COMPOSITION :

POM

Each film coated tablet contains :

Tadalafil	20 mg
Excipients	Q.S.
Approved colour used	

### THERAPEUTIC CLASS :

Phosphodiesterase type 5 (PDE5) Inhibitor

### PHARMACOLOGICAL ACTION:

Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the absence of sexual stimulation.

#### *Pharmacokinetics:*

Tadalafil is readily absorbed after oral administration and  $C_{max}$  is achieved at a median time of 2 hours after dosing. At therapeutic concentrations, 94% of tadalafil in plasma is bound to proteins. Protein binding is not affected by impaired renal function. Tadalafil is predominantly metabolised by the cytochrome P450 (CYP) 3A4 isoform. The major circulating metabolite is the methylcatechol glucuronide. The mean oral clearance for tadalafil is 2.5 l/h and the mean half-life is 17.5 hours in healthy subjects. Tadalafil is excreted predominantly as inactive metabolites, mainly in the faeces (approximately 61% of the dose) and to a lesser extent in the urine (approximately 36% of the dose).

### INDICATIONS:

TADALIN-20 is indicated in treatment of erectile dysfunction.

### CONTRA-INDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients
- cardiac patient with myocardial infarction within the last 90 days, with unstable angina or angina occurring during sexual intercourse, with greater heart failure in the last 6 months, with uncontrolled arrhythmias, hypotension (<90/50mmHg), or uncontrolled hypertension, with a stroke within the last 6 months.
- Patients who are using any form of organic nitrate.

### SPECIAL PRECAUTIONS AND WARNINGS:

A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes, before pharmacological treatment is considered.

Visual defects and cases of Non-arteritic anterior ischaemic optic neuropathy (NAION) have been reported in connection with the intake of TADALIN-20 and other PDE5 inhibitors. The patient should be advised that in case of sudden visual defect, he should stop taking TADALIN-20.

Patients who experience erections lasting 4 hours or more should be instructed to seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

TADALIN-20 should be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis, or Peyronie's disease) or in patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma, or leukaemia).

The safety and efficacy of combinations of TADALIN-20 and other treatments for erectile dysfunction have not been studied. Therefore, the use of such combinations is not recommended.

*Pregnancy and Lactation:* TADALIN-20 is not indicated for use in women.

### DOSAGE AND ADMINISTRATION:

TADALIN-20 may be taken with or without food.

Use in Adult Men (over 18 years):

10 mg as needed prior to sexual activity. Increase to 20 mg based upon efficacy/tolerability. Erectile function may be improved for up to 36 hours following a single dose. Not to be taken more than once per day.

**Hepatic Impairment:**

*Mild or Moderate:* The dose should not exceed 10 mg once per day.

*Severe:* Use is not recommended.

**Renal Impairment:**

Patients with creatinine clearance 30 to 50 mL/min: A starting dose of 5 mg not more than once per day is recommended, and the maximum dose is 10 mg not more than once in every 48 hours.

*Creatinine clearance less than 30 mL/min or on hemodialysis:* The maximum dose is 5 mg not more than once in every 72 hours.

*Use in Children and Adolescents:* TADALIN-20 should not be used in individuals below 18 years of age.

#### **ADVERSE EFFECTS :**

*Very common:* Headache, Dyspepsia

*Common:* Dizziness, Flushing, Nasal congestion, Back pain, Myalgia

*Uncommon:* Hypersensitivity reactions, Blurred vision, Sensations described as eye pain, Tachycardia, Palpitations, Hypotension (more commonly reported when tadalafil is given to patients who are already taking antihypertensive agents), Hypertension, Abdominal pain, Gastro-oesophageal reflux, Rash, Hyperhydrosis (sweating), Chest pain

*Rare:* Stroke (including haemorrhagic events), Syncope, Transient ischaemic attacks, Migraine, Seizures, Transient amnesia, Visual field defect, Swelling of eyelids, Conjunctival hyperaemia, Non-arteritic anterior ischaemic optic neuropathy (NAION), Retinal vascular occlusion, Sudden hearing loss, Myocardial infarction, Unstable angina pectoris, Ventricular arrhythmia, Epistaxis, Urticaria, Stevens-Johnson syndrome, Exfoliative dermatitis, Prolonged erections, Priapism, Facial oedema, Sudden cardiac death

#### **DRUG INTERACTIONS:**

Tadalafil can potentiate the hypotensive effects of nitrates, alpha blockers, antihypertensives or alcohol.

CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) increase Tadalafil exposure. For concomitant use with potent CYP3A4 inhibitors, dose adjustment may be needed.

CYP3A4 inducers (e.g. rifampin) decrease Tadalafil exposure.

#### **OVERDOSAGE:**

Single doses of up to 500mg have been given to healthy subjects, and multiple daily doses up to 100mg have been given to patients. Adverse events were similar to those seen at lower doses.

In cases of overdose, standard supportive measures should be adopted, as required. Haemodialysis contributes negligibly to tadalafil elimination.

#### **PRESENTATION:**

Blister pack

#### **STORAGE CONDITION:**

Store below 30°C. Protect from light.

Manufactured by :

 **LINCOLN**  
PHARMACEUTICALS LTD.

Trimul Estate, At. & Post.- Khatraj,  
Tal.-Kalol, Dist.- Gandhinagar, Gujarat, India

E-mail : [info@lincolnpharma.com](mailto:info@lincolnpharma.com)

Website : [www.lincolnpharma.com](http://www.lincolnpharma.com)