1.4.1

Prescribing Information (Summary of Product Characteristics)

1.4.1.1 Name of the medicinal Product

Tadalafil Tablets 20 mg (TADALIN-20)

1.4.1.1.1 Strength

20 mg/tab

1.4.1.1.2 Pharmaceutical Form

Oral Tablets

1.4.1.2 Qualitative and Quantitative Composition

1.4.1.2.1 Qualitative declaration

Tadalafil

1.4.1.2.2 Quantitative declaration

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity/ Tablet (mg)	Reason for Inclusion
01	Tadalafil	IHS	20.00	Phosphodiesterase type 5 (PDE5) Inhibitor
02	Lactose (Lactose Monohydrate)	BP	170.0	Diluent
03	Sodium Lauryl Sulfate	BP	2.000	Surfactant
04	Croscarmellose Sodium	USP-NF	5.000	Super Disintegrant
05	Low-substituted Hydroxy Propyl Cellulose	USP-NF	5.000	Granulating agent
06	Purified water	BP	Q.S.	Solvent
07	Microcrystalline Cellulose (PH 102)	BP	70.00	Disintegrant

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity/ Tablet (mg)	Reason for Inclusion
08	Croscarmellose Sodium	USP-NF	10.00	Super Disintegrant
09	Magnesium Stearate	BP	3.000	Lubricant
10	Hypromellose (Methocel E-15)	BP	4.800	Coating agent
11	Titanium Dioxide	BP	1.000	Opacifier
12	Colour Ponceau 4R Lake	IHS	1.000	Colouring agent
13	Diethyl Phthalate	BP	1.200	Plasticizer
14	Dichloromethane	BP	96.00	Solvent
15	Isopropyl alcohol	BP	64.00	Solvent

1.4.1.3 Pharmaceutical Form

Oral Tablet

Reddish pink colour, diamond shaped, film coated tablets, plain on both sides.

1.4.1.4 Clinical Particulars

1.4.1.4.1 Therapeutic Indications

Tadalin-20 is indicated for the treatment of erectile dysfunction.

1.4.1.4.2 Posology and Method of Administration

Use in Adult Men: Once per day may be taken with or without food.

It may be taken at least 30 minutes prior to sexual activity and it is not recommended for continue daily use.

Use in Elderly Men: Dose adjustments are not required in elderly patients.

Use in Men with Impaired Renal Function: Dose adjustments are not required in patients with mild to moderate renal impairment. For patients with severe renal impairment, 10 mg is the maximum recommended dose.

Use in Men with impaired Hepatic Function: Once-a-day dosing has not been evaluated in patients with hepatic impairment; therefore if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician.

Use in Men with Diabetes: Dose adjustments are not required in diabetic patients.

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

1.4.1.4.3 Contraindications

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.

1.4.1.4.4 Special Warnings and Special Precautions for Use

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 Tadalafil.

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) & also when prescribing TADALIN-20 to patients using

potent CYP3A4 inhibitors (ritonavir, sequinavir, ketoconazole, itracondazole and erythromycin), as increased tadalafil exposure (AUC) has been observed if the medicines are combined.

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.

WARNING: THIS PRODUCT CONATINS LACTOSE.

1.4.1.4.5 Interaction with other medicinal products and other forms of interaction

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

CYP3A4 inhibitors (e.g. Ketoconazole, Ritonavir) increases tadalafil exposure. For Concomitant use with CYP3A4 inhibitors , dose adjustment may be needed.

CYP3A4 inducers (e.g Rifampicin.) decreases tadalafil exposure.

1.4.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy and Lactation: Tadalafil is not indicated for use in women.

1.4.1.4.7 Effects on ability to Drive and use Machines

No data Available.

1.4.1.4.8 Undesirable Effects

Very common: Headache, Dyspepsia

Common; Dizziness, Palpitation, Flushing, Nasal congestion, Abdominal pain, Gastro-oesophageal reflux, Back pain, Myalgia.

Uncommon: hypersensitivity reactions, blurred vision, sensations described as eye pain, swelling of eyelids, conjunctivital hyperaemia, tachycardia, hypertension (more commonly reported when taladalafil is given to patients who are already taking antihypertensive agents), rash, urticarial, hyperhidrosis (sweating), hypertension, chest pain.

Rare: stroke, syncope, transient ischaemic attacks, migraine, visual field defects, myocardial infractions, prolonged erections, facial oedema

1.4.1.4.9 Overdose

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

1.4.1.5 Pharmacological Properties

1.4.1.5.1 Pharmacodynamics Properties

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.

1.4.1.5.2 Pharmacokinetic Properties

Tadalafil is readily absorbed after oral administration and Cmax 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).

1.4.1.5.3 Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

1.4.1.6 Pharmaceutical Particulars

1.4.1.6.1 List of Excipients

Lactose (Lactose Monohydrate) BP

Sodium Lauryl Sulfate BP

Croscarmellose Sodium USP-NF

Low-substituted Hydroxy Propyl Cellulose USP-NF

Purified Water BP

Microcrystalline Cellulose (PH 102) BP

Magnesium Stearate BP

Hypromellose (Methocel E-15) BP

Titanium Dioxide BP

Colour Ponceau 4R Lake IHS

Dichloromethane BP

Isopropyl alcohol BP

1.4.1.6.2 Incompatibilities

Not applicable.

1.4.1.6.3 Shelf Life

36 months

1.4.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

1.4.1.6.5 Nature and Contents of Container

Reddish pink colour, diamond shaped, film coated tablets, plain on both sides. Such 4 Tablets are packed in a Blister Pack. Such 1 Blister is packed in a printed Carton with Packing Insert.

1.4.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.4.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.4.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-02764-665000
Fax: +91-02764-281809
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

1.4.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-02764-665000
Fax: +91-02764-281809
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

1.4.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.4.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.4.1.10 Date of Revision of the Text

1.4.1.11 Dosimetry (If Applicable)

Not Applicale

1.4.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable