	Averageweightofuncoatedtablet=180mg±7.5%

BatchSize:1.0Lac

3. PharmaceuticalForm

Darkgreen/lightgreencolouredcap&bodyhardgelatincapsulesofsize“4”containingwhite powder.

4. Clinicalparticulars

4.1 Therapeuticindications

Tadalafil(Cialis)isusedtotreaterectiledysfunction(ED,impotence;inabilitytogetorkeepan erection),andthesymptomsofbenignprostatichyperplasia(BPH;anenlargedprostate)which

includedifficultyurinating(hesitation,dribbling,weakstream,andincompletebladderemptying), painful urination, and urinary frequency and urgency in adult men.

4.2 Dosage

Condition	RecommendedDose
ErectiledysfunctioninadultMen	10 mg taken prior to anticipated sexual activity and with or without food. If Tadalafil 10 mg does not produce an adequate effect, 20 mg might be tried. It may be taken at least 30 minutes prior to sexual activity.
Pulmonaryarterialhypertension	40mg(2x 20mg)takenoncedailywithorwithoutfood.
MenwithDiabetes	In *a*dult men with erectile dysfunction the dose adjustments are not required.
Paediatricpopulation:	Notrecommended

4.3 Contraindications

Hypersensitivitytotheactivesubstancesorto anyofthe excipients.
Tadalafil must not be used in men with cardiac disease for whom sexual activity is inadvisable.
Physiciansshouldconsiderthepotentialcardiacriskofsexualactivityinpatientswithpre-existing cardiovascular disease.

4.4 Specialwarningsandprecautionsforuse

Before treatment with Tadalafil: A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes, before pharmacological treatment is considered.
Vision: Visual defects and cases of NAION have been reported in connection with the intake oftadalafil and other PDE5 inhibitors.The patient should be advised that in case of sudden visual defect, he should stop taking Tadalafil and consult a physician immediately
Renal and hepatic impairment: Due to increased tadalafil exposure (AUC), limited clinical experience and the lack of ability to influence clearance by dialysis, once-a-day dosing of Tadalafil is not recommended in patients with severe renal impairment.
*Priapismandanatomicaldeformationofthepenis:*Patientswhoexperienceerectionslasting4hoursor 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. Tadalafil should be used with cautionin patients with anatomical deformation of the penis or in patients who have conditions which may predispose them to priapism.
Tadalafil and other treatments for erectile dysfunction: The safety and efficacy of combinations of tadalafil and other PDE5 inhibitors or other treatments for erectile dysfunction have not been studied. The patients should be informed not to take Tadalafil in such combinations.
Lactose: Tadalafil contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interactionwithothermedicinalproductsandotherformsofinteraction

*CytochromeP450 inducers:*ACYP3A4 inducer, rifampicin reduced tadalafil AUC by 88 %, relativeto theAUCvaluesfortadalafilalone(10mg).Thisreducedexposurecanbeanticipatedtodecreasethe

efficacy of tadalafil; the magnitude of decreased efficacy is unknown. Other inducers of CYP3A4, such as phenobarbital, phenytoin, and carbamazepine, may also decrease plasma concentrations of tadalafil.
*Anti-hypertensives(includingcalciumchannelblockers):*Theco-administrationofdoxazosin(4mg and8mgdaily)andtadalafil(5mgdailydoseand20mgasasingledose)increasestheblood pressure-lowering effect of this alpha-blocker in a significant manner. This effect lasts at least 12 hours and may be symptomatic, including syncope. Therefore, this combination is not recommended.
Riociguat: Concomitant use of riociguat with PDE5 inhibitors, including tadalafil, is contraindicated
*Aspirin:*Tadalafil(10mgand20mg)didnotpotentiatetheincreaseinbleedingtimecausedby acetylsalicylic acid.

4.6 Fertility,pregnancyandlactation

*Pregnancy:*ThereareliteddatafromtheuseofTadalafilinpregnantwomen.Itispreferableto avoid the use of Tadalafil during pregnancy.
*Breast-feeding:*ArisktothesucklingchildcannotbeexcludedTadalafilshouldnotbeusedduring breast-feeding.

4.7 Effectsonabilityto driveandusemachines

TadalafilTabletshasnegligibleinfluenceontheabilitytodriveoruse machines.

4.8 Undesirableeffects

Commonsideeffectsincludeflushing(rednessorwarmthoftheface,neck,orchest),headaches, stomach upset, diarrhea, flu-like symptoms (such as stuffy nose, sneezing, or sore throat), memoryproblems,muscleorbackpain,nausea,lowbloodpressure,dizziness,blurredvisionand changes in color vision, abnormal ejaculation, and prolonged erections (priapism).

4.9 Overdose

Incasesofoverdose,standardsupportivemeasuresshouldbeadopted,asrequired.Haemodialysis contributes negligibly to tadalafil elimination.

4.10 PharmacodynamicEffects

*Pharmacotherapeuticgroup:*Urological,Drugsusedinerectiledysfunction.
Mechanismofaction:
Tadalafilisaselective,reversibleinhibitorofcyclicguanosinemonophosphate(cGMP)-specific phosphodiesterase type 5 (PDE5).
Erectiledysfunction
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 treatment of erectile dysfunction in the absence of sexual stimulation.
Pulmonaryarterialhypertension
Pulmonary arterial hypertension is associated with impaired release of nitric oxide by the vascular endothelium and consequent reduction of cGMP concentrations within the pulmonary vascularsmooth muscle. PDE5 is the predominant phosphodiesterase in the pulmonary vasculature. Inhibition of PDE5 by tadalafil increases the concentrations of cGMP resulting in relaxation of the pulmonary vascular smooth muscle cell and vasodilation of the pulmonary vascular bed.

4.11 PharmacokineticProperties

Absorption

Tadalafil is readily absorbed after oral administration and the mean maximum observed plasma concentration (Cmax)is achieved at amedian timeof2 hours afterdosing. Absolutebioavailabilityof tadalafil following oral dosing has not been determined.

The rate and extent of absorption of tadalafil are not influenced by food, thus Tadalafil Tablets maybetaken with orwithout food. Thetimeofdosing (morning versus evening)had no clinically relevant effects on the rate and extent of absorption.

Distribution

The mean volume of distribution is approximately 63 liters, indicating that tadalafil is distributed into tissues. At therapeuticconcentrations, 94%oftadalafil in plasmais bound to proteins. Protein binding is not affected by impaired renal function.

Lessthan0.0005%ofthe administereddoseappearedinthesemenofhealthy subjects.

Biotransformation

Tadalafil is predominantly metabolised by the cytochrome P450 (CYP) 3A4 isoform. The major circulating metabolite is the methylcatechol glucuronide. This metabolite is at least 13,000-fold less potent than tadalafil for PDE5. Consequently, it is not expected to be clinically active at observed metabolite concentrations.

Elimination:

Themean oral clearance fortadalafil is 2.5 l/h and themean half-lifeis 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).

4.13 PharmaceuticalParticulars:

List of Excipients:

1. Tadalafil
2. Starch
3. Povidone
4. Lactose
5. IsopropylAlcohol
6. SodiumAnhydrousSilica
7. PurifiedTalc
8. MagnesiumStearate
9. EmptyGelatinCapsulesSize“4”DarkGreen/LightGreen

4.14 Incompatibilities

NotApplicable

4.15 Shelflife

36 Months.

4.16 Specialprecautionsfordisposalandotherhandling

Anyunusedmedicinalproductorwastematerialshouldbedisposedofinaccordancewithlocal requirements.

4.17 Natureandcontentsofcontainer

10 x 10 Tablets.

ManufacturedBy:
HabPharmaceuticals&ResearchLtd.,
10, Pharmacity, Selaqui,
Dehradun,Uttarakhand-248011,
India

Marketingauthorizationholder
HabPharmaceuticals&ResearchLtd.,
10, Pharmacity, Selaqui,
Dehradun,Uttarakhand–248011
India