Bharat Parenterals Limited
Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

AFRIFIL 20
SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product:

1.1 name of the medicinal product:

Generic Name/INN Name: Tadalafil Tablets USP 20 mg

Trade Name: AFRIFIL 20

1.2 Strength:

Each film coated tablet contains:

Tadalafil USP.....20 mg

Excipients.....q.s.

Colour: Yellow Oxide of Iron

1.3 Pharmaceutical form:

Solid Oral Dosage form (Tablet)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Spec.	Label Claim (mg)	Std. Qty. / Tab in mg	% w/w	Function
1.	Tadalafil*	USP	20.00	20.00	3.92%	Active Ingredient
2.	Lactose monohydrate	BP	--	245.00	48.04%	Diluent
3.	Croscarmellose Sodium	BP	--	20.00	3.92%	Super Disintegrant
Binder				--		
4.	Hydroxypropyl Cellulose (HPC-L)	BP	--	3.00	0.59%	Binder
5.	Sodium Lauryl Sulfate	BP	--	5.00	0.98%	Solubilizer
6.	Purified water***	BP	--	70.00	--	Binder solvent
Lubrication						
7.	Microcrystalline cellulose (Grade –pH- 112)**	BP	--	182.00	35.69%	Diluent
8.	Croscarmellose Sodium	BP	--	20.00	3.92%	Super Disintegrant
9.	Magnesium stearate	BP	--	5.00	0.98%	Lubricant
Total weight of the uncoated tablet				**500.00**	--	--
Film Coating						
10.	Instacoat Aqua-III (A03R00422)	IHS	--	10.00	1.96%	Coating material
11.	Purified water***	BP	--	68.00	--	Solvent for coating
Total weight of the coated tablet				**510.00**	**100%**	--

Note:

* The quantity of the Tadalafil has to be calculated as per Assay & water content.

** Quantity of Microcrystalline cellulose Grade 102 will vary as per the quantity of the APIs

*** Water that evaporated during the process

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AFRIFIL 20
SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

3. Pharmaceutical form:

Dosage Form:

Solid Oral Dosage form (Tablet)

Visual & Physical characteristics of the product:

A cream coloured diamond shape, biconvex, film coated tablets, having embossed 'CHCL' on one side and symbol of CHANRAI on other side of the tablets.

4. Clinical particulars

4.1. Therapeutic indications:

Treatment of erectile dysfunction in adult males.

In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.

Tadalafil tablet is not indicated for use by women.

4.2. Posology and method of administration:

Posology

Erectile dysfunction in adult Men.

In general, the recommended dose is 10 mg taken prior to anticipated sexual activity and with or without food.

In those patients in whom 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.

The maximum dose frequency is once per day.

Tadalafil 10 and 20 mg is intended for use prior to anticipated sexual activity and it is not recommended for continuous daily use.

In patients who anticipate a frequent use of Tadalafil tablet (i.e., at least twice weekly) a once daily regimen with the lowest doses of Tadalafil tablet might be considered suitable, based on patient choice and the physician's judgement.

The appropriateness of continued use of the daily regimen should be reassessed periodically.

Special Populations

Elderly Men

Dose adjustments are not required in elderly patients.

Men with Renal Impairment

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.

Once-a-day dosing of 2.5 or 5 mg tadalafil both for the treatment of erectile dysfunction or benign prostatic hyperplasia is not recommended in patients with severe renal impairment.

Men with Hepatic Impairment

For the treatment of erectile dysfunction using on-demand Tadalafil tablet the recommended dose of Tadalafil tablet is 10 mg taken prior to anticipated sexual activity and with or without food. There is limited clinical data on the safety of Tadalafil tablet in patients with severe hepatic impairment (Child-Pugh class C); if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician. There are no available data about the administration of doses higher than 10mg of tadalafil to patients with hepatic impairment.

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Once-a-day dosing both for the treatment of erectile dysfunction and benign prostatic hyperplasia 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.
Men with Diabetes
Dose adjustments are not required in diabetic patients.
Paediatric population
There is no relevant use of Tadalafil tablet in the paediatric population with regard to the treatment of erectile dysfunction.
Method of administration
Oral administration.

4.3. Contraindications
Hypersensitivity to the active substance or to any of the excipients.
In clinical studies, tadalafil was shown to augment the hypotensive effects of nitrates. This is thought to result from the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway. Therefore, administration of Tadalafil tablet to patients who are using any form of organic nitrate is contraindicated.
Tadalafil tablet must not be used in men with cardiac disease for whom sexual activity is inadvisable. Physicians should consider the potential cardiac risk of sexual activity in patients with pre-existing cardiovascular disease.
The following groups of patients with cardiovascular disease were not included in clinical trials and the use of tadalafil is therefore contraindicated:

- patients with myocardial infarction within the last 90 days,
- patients with unstable angina or angina occurring during sexual intercourse,
- patients with New York Heart Association Class 2 or greater heart failure in the last 6 months,
- patients with uncontrolled arrhythmias, hypotension (<90/50 mm Hg), or uncontrolled hypertension,
- patients with a stroke within the last 6 months.

Tadalafil tablet is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure.
The co-administration of PDE5 inhibitors, including tadalafil, with guanylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension.

4.4. Special warnings and precautions for use:
Before treatment with Tadalafil tablet
A medical history and physical examination should be undertaken to diagnose erectile dysfunction or benign prostatic hyperplasia and determine potential underlying causes, before pharmacological treatment is considered.
Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Tadalafil

has vasodilator properties, resulting in mild and transient decreases in blood pressure and as such potentiates the hypotensive effect of nitrates.

The evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following an appropriate medical assessment. It is not known if Tadalafil tablet is effective in patients who have undergone pelvic surgery or radical non-nerve-sparing prostatectomy.

Cardiovascular

Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischaemic attacks, chest pain, palpitations and tachycardia, have been reported either post marketing and/or in clinical trials. Most of the patients in whom these events have been reported had pre-existing cardiovascular risk factors. However, it is not possible to definitively determine whether these events are related directly to these risk factors, to Tadalafil tablet, to sexual activity, or to a combination of these or other factors.

In patients who are taking alpha1 blockers, concomitant administration of Tadalafil tablet may lead to symptomatic hypotension in some patients. The combination of tadalafil and doxazosin is not recommended.

Vision

Visual defects and cases of NAION have been reported in connection with the intake of Tadalafil tablet and other PDE5 inhibitors. Analyses of observational data suggest an increased risk of acute NAION in men with erectile dysfunction following exposure to tadalafil or other PDE5 inhibitors. As this may be relevant for all patients exposed to tadalafil, the patient should be advised that in case of sudden visual defect, he should stop taking Tadalafil tablet and consult a physician immediately.

Decreased or sudden hearing loss

Cases of sudden hearing loss have been reported after the use of tadalafil. Although other risk factors were present in some cases (such as age, diabetes, hypertension and previous hearing loss history) patients should be advised to stop taking tadalafil and seek prompt medical attention in the event of sudden decrease or loss of hearing.

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 tablet is not recommended in patients with severe renal impairment.

There is limited clinical data on the safety of single-dose administration of Tadalafil tablet in patients with severe hepatic insufficiency (Child-Pugh Class C). Once-a-day administration has not been evaluated in patients with hepatic insufficiency. If Tadalafil tablet is prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician.

Hepatic impairment

There is limited clinical data on the safety of single-dose administration of Tadalafil tablet in patients with severe hepatic insufficiency (Child-Pugh Class C). If Tadalafil tablet is prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician.

Priapism and anatomical deformation of the penis 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.