

Tadalipits
tadalafil
5mg film-coated tablets

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1. Name of the medicinal product

Tadalipits

2. Qualitative and quantitative composition

Each 5mg tablet contains 5mg tadalafil.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet.

Light yellow to yellow, round, biconvex, unscored, film coated tablets with white to off white core.

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.

Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

Tadalafil 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 10mg taken prior to anticipated sexual activity and with or without food. In those patients in whom Tadalafil 10mg does not produce an adequate effect, 20mg might be tried. It may be taken at least 30 minutes prior to sexual activity.

The maximum dose frequency is once per day.

Tadalafil 10mg and 20mg 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 (i.e., at least twice weekly) a once daily regimen with the lowest doses of Tadalafil might be considered suitable, based on patient choice and the physician's judgement.

In these patients, the recommended dose is 5mg taken once a day at approximately the same time of day. The dose may be decreased to 2.5mg once a day based on individual tolerability.

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

Benign prostatic hyperplasia in adult men

The recommended dose is 5 mg, taken at approximately the same time every day with or without food. For adult men being treated for both benign prostatic hyperplasia and erectile dysfunction the recommended dose is also 5 mg taken at approximately the same time every day. Patients who are unable to tolerate tadalafil 5 mg for the

treatment of benign prostatic hyperplasia should consider an alternative therapy as the efficacy of tadalafil 2.5mg for the treatment of benign prostatic hyperplasia has not been demonstrated.

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, 10mg is the maximum recommended dose for on-demand treatment. 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. (See sections 4.4 and 5.2.)

Men with Hepatic Impairment

For the treatment of erectile dysfunction using on-demand Tadalafil the recommended dose of Tadalafil is 10mg taken prior to anticipated sexual activity and with or without food. There is limited clinical data on the safety of Tadalafil 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.

Once-a-day dosing of Tadalafil for both 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. (See sections 4.4 and 5.2.)

Men with Diabetes

Dose adjustments are not required in diabetic patients.

Paediatric population

There is no relevant use of Tadalafil in the paediatric population with regard to the treatment of erectile dysfunction.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity Reactions Due to Usage Such As

- 1- Stevens-Johnson Syndrome
- 2- Exfoliative Dermatitis

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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 to patients who are using any form of organic nitrate is contraindicated. (See section 4.5.)

Tadalafil, 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.