

TADALAFIL

TADALAFIL 5 mg

Presented as box with 6 Blisters containing 15 capsules per carton.

DESCRIPTION

Tadalafil is a reversible inhibitor of cyclic guanosine monophosphate (cGMP) – specific phosphodiesterase type 5 (PDE5) in the smooth muscle of the corpus cavernosum, the prostate, the bladder and their vascular supply. In the corpus cavernosum, when sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP. 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. In the smooth muscle of the prostate, bladder and their vascular supply, the effect of PDE5 inhibition on cGMP concentration results in vascular relaxation and increases blood perfusion which may be the mechanism by which symptoms of benign prostatic hyperplasia are reduced. These vascular effects may be complemented by inhibition of bladder afferent nerve activity and smooth muscle relaxation of the prostate and bladder.

INDICATIONS

TADALAFIL is indicated for the treatment of:

- erectile dysfunction (ED) in adult males;
- moderate to severe lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) in adult males.

CONTRAINDICATIONS

Nitrates and tadalafil must not be used concomitantly. Co-administration of tadalafil with nitric oxide donors, organic nitrates or organic nitrites in any form either regularly or intermittently is contraindicated. Drugs which must not be used concomitantly include, but are not limited to, glyceryl trinitrate (injection, tablets, sprays or patches), isosorbide salts, sodium nitroprusside, amyl nitrite, nicorandil or organic nitrates in any form. In clinical studies, tadalafil was shown to potentiate the hypotensive effects of both acute and chronic nitrate administration. This is thought to result from the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway.

DOSAGE AND DIRECTIONS FOR USE

For erectile dysfunction in adult males - on-demand dosing:

The recommended dose of Tadalafil is either 10 mg or 20 mg, taken prior to anticipated sexual activity. The maximum recommended dose is 20 mg. The maximum recommended dosing frequency is once per day.

For erectile dysfunction in adult males - once-a-day dosing:

In patients who anticipate a frequent use of Tadalafil (i.e. at least twice weekly), a once daily regimen with the lowest dose 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 must not exceed 5mg daily. The dose may be decreased to 2.5mg once a day based on individual tolerability.

DRUG INTERACTIONS

Tadalafil is not expected to cause clinically significant inhibition or induction of the clearance of drugs metabolised by CYP450 isoforms. Studies have confirmed that tadalafil does not inhibit or induce CYP450 isoforms, including CYP1A2, CYP3A4, CYP2C9, CYP2C19, CYP2D6 and CYP2E1.

PRESENTATION

6 Blisters containing 15 capsules per carton.

STORAGE

Store below 25°C. Store in the original package.