



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TADALAFIL TABLETS safely and effectively. See full prescribing information for TADALAFIL TABLETS.

TADALAFIL TABLETS, for oral use
 Initial U.S. Approval: 2005

Warnings and Precautions (5.1)
 Recent Major Changes
 Administration of tadalafil tablets to patients using any form of organic nitrate is contraindicated. Tadalafil tablets should not be administered to patients with a history of priapism (4.1).

INDICATIONS AND USAGE
 Tadalafil tablet is a phosphodiesterase (PDE5) inhibitor indicated for the treatment of:
 • Erectile dysfunction (ED) in men
 • The signs and symptoms of benign prostatic hyperplasia (BPH) (1.2)
 • ED and the signs and symptoms of BPH in men (1.3)
 Tadalafil tablets may also be used to treat pulmonary hypertension (PH) (1.4).

ADVERSE REACTIONS
 Tadalafil tablets may be taken without regard to food (2.5).

DOSEAGE FORMS AND STRENGTHS
 Tablets: 2 mg, 5 mg, 10 mg, 20 mg (2.1)

CONTRAINDICATIONS
 Administration of tadalafil tablets to patients using any form of organic nitrate is contraindicated. Tadalafil tablets should not be administered to patients with a history of priapism (4.1).

Warnings and Precautions
 • History of known serious hypersensitivity reaction to tadalafil tablets or ADICORR (4.2)
 • Administration with guanylate cyclase (GC) stimulators (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 5.15, 5.16, 5.17, 5.18, 5.19, 5.20, 5.21, 5.22, 5.23, 5.24, 5.25, 5.26, 5.27, 5.28, 5.29, 5.30, 5.31, 5.32, 5.33, 5.34, 5.35, 5.36, 5.37, 5.38, 5.39, 5.40, 5.41, 5.42, 5.43, 5.44, 5.45, 5.46, 5.47, 5.48, 5.49, 5.50, 5.51, 5.52, 5.53, 5.54, 5.55, 5.56, 5.57, 5.58, 5.59, 5.60, 5.61, 5.62, 5.63, 5.64, 5.65, 5.66, 5.67, 5.68, 5.69, 5.70, 5.71, 5.72, 5.73, 5.74, 5.75, 5.76, 5.77, 5.78, 5.79, 5.80, 5.81, 5.82, 5.83, 5.84, 5.85, 5.86, 5.87, 5.88, 5.89, 5.90, 5.91, 5.92, 5.93, 5.94, 5.95, 5.96, 5.97, 5.98, 5.99, 6.00, 6.01, 6.02, 6.03, 6.04, 6.05, 6.06, 6.07, 6.08, 6.09, 6.10, 6.11, 6.12, 6.13, 6.14, 6.15, 6.16, 6.17, 6.18, 6.19, 6.20, 6.21, 6.22, 6.23, 6.24, 6.25, 6.26, 6.27, 6.28, 6.29, 6.30, 6.31, 6.32, 6.33, 6.34, 6.35, 6.36, 6.37, 6.38, 6.39, 6.40, 6.41, 6.42, 6.43, 6.44, 6.45, 6.46, 6.47, 6.48, 6.49, 6.50, 6.51, 6.52, 6.53, 6.54, 6.55, 6.56, 6.57, 6.58, 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