

# Tadalafil

*translated from original Russian leaflet by RussianMeds Store*

<https://russianmeds.com>

**Name in Cyrillic:** Тадалафил

## **Brand Names:**

Cialis (Сиалис), Fremitus (Фреймитус), Tadalafil Vertex (Тадалафил Вертекс), Dynamico Long (Динамико Лонг)

**Pharmacologic effect:** Treatment of erectile dysfunction. PDE5 inhibitor.

## **Pharmacologic effect:**

Tadalafil is a reversible selective inhibitor of specific PDE5 cGMP. When sexual arousal causes local release of nitric oxide, PDE5 inhibition by tadalafil results in an increase in cGMP levels in the corpus cavernosum of the penis. The consequence of this is the relaxation of the smooth muscles of the arteries and the flow of blood to the tissues of the penis, which causes an erection. Tadalafil is ineffective in the absence of sexual stimulation.

## **Pharmacokinetics:**

After oral administration, tadalafil is rapidly absorbed. Cmax is reached after an average of 2 hours. The rate and degree of absorption do not depend on food intake. The pharmacokinetics of tadalafil in healthy individuals is linear with respect to time and dose. In the dose range from 2.5 to 20 mg AUC increases in proportion to the dose. Css in plasma are achieved within 5 days when taking the drug 1 time / day.

The pharmacokinetics of tadalafil in patients with erectile dysfunction is similar to the pharmacokinetics of the drug in individuals without erectile dysfunction.

**Indications:** Erection disorders.

**Contraindications:** Simultaneous administration of drugs containing any organic nitrates; children and adolescents up to 18 years of age; hypersensitivity to tadalafil.

## **Use with caution:**

In patients with severe renal insufficiency ( $CC \leq 30$  ml / min) and severe liver failure tadalafil should be used with extreme caution and only if absolutely necessary.

During treatment with tadalafil in patients with moderate renal insufficiency ( $CC$  from 31 to 50 ml / min), back pain was more common compared with patients with mild renal insufficiency ( $CC$  from 51 to 80 ml / min) or healthy volunteers .

In patients with  $CC \leq 50$  ml/min, tadalafil should be used with caution.

Therefore, the treatment of erectile dysfunction, incl. with the use of tadalafil, should not be performed in men with heart conditions in which sexual activity is not recommended.

The potential risk of developing complications during sexual activity in patients with diseases of the cardiovascular system should be taken into account: myocardial infarction within the last 90 days; unstable angina or angina that occurs during intercourse; chronic heart failure (functional class II and above according to the NYHA classification) that has developed within the last 6 months; uncontrolled heart rhythm disturbances; arterial hypotension (BP less than 90/50 mm Hg) or uncontrolled arterial hypertension; stroke within the last 6 months.

Tadalafil should be used with caution in patients with a predisposition to priapism (for example, with sickle cell anemia, multiple myeloma or leukemia) or in patients with anatomical deformity of the penis (for example, with angulation, cavernous fibrosis or Peyronie's disease).

The patient should be informed of the need for immediate medical attention in the event of an erection lasting 4 hours or more. Untimely treatment of priapism leads to damage to the tissues of the penis, as a result of which a long-term loss of potency may occur.

During using of tadalafil, no cases of priapism were reported.

It is not recommended to use tadalafil in combination with other treatments for erectile dysfunction.

**Side effects:**

Most common: headache, dyspepsia.

Possible: back pain, myalgia, nasal congestion, flushing of the face.

Rarely: swelling of the eyelids, eye pain, conjunctival hyperemia, dizziness.

**Interaction:**

Tadalafil is mainly metabolized by the CYP3A4 enzyme. The selective CYP3A4 inhibitor ketoconazole increases AUC by 107%, while rifampicin reduces it by 88%.

Although specific interactions have not been studied, it can be assumed that protease inhibitors such as ritonavir and saquinavir, as well as CYP3A4 inhibitors such as erythromycin and itraconazole, increase the activity of tadalafil.

With the simultaneous administration of an antacid (magnesium hydroxide / aluminum hydroxide) and tadalafil, the rate of absorption of tadalafil decreases without changing its AUC.

Tadalafil enhances the hypotensive effect of nitrates. This occurs as a result of the additive action of nitrates and tadalafil on nitric oxide and cGMP metabolism. Therefore, the use of tadalafil in patients receiving nitrates is contraindicated.

**Dosing and Administration:**

Middle-aged men are recommended to take a dose of 20 mg at least 16 minutes before the expected sexual activity, regardless of the meal. Patients may attempt intercourse at any time within 36 hours after ingestion in order to establish an optimal response time to tadalafil. The maximum frequency of admission is 1 time / day.

**Manufacturer:**

Cialis : Eli Lilly (Switzerland)

Fremitus : Ozon Pharma (Russia)

Tadalafil Vertex : Vertex Pharma (Russia)

Dynamico Long : Teva (Israel)

**Reliable supplier with fast Worldwide shipping:**

RussianMeds Online Store

<https://russianmeds.com>

**Storage:**

The temperature is not above 25 °C (77 °F)

Keep out of the reach of children.