Sildenafil

translated from original Russian leaflet by RussianMeds Store https://russianmeds.com

Name in Cyrillic: Силденафил

Brand Names:

Sildenafil-SZ (Силденафил-С3), Viagra (Виагра), Sildenafil Vertex (Силденафил Вертекс), Dynamico (Динамико), Vizarsin (Визарсин), Maxigra (Максигра), Sildenafil Renewal (Силденафил Реневал)

Pharmachologic effect: improving erectile function

Pharmacokinetics:

Sildenafil is rapidly absorbed from the gastrointestinal tract. Absolute bioavailability is 25-63%, with an average of 41%. Cmax is achieved within 30-120 minutes (average 60 minutes). When taken with fatty foods, the absorption rate slows down, Cmax decreases by an average of 29%, and the time to achieve it increases by 60 minutes. Pharmacokinetics in the dose range of 25-100 mg is linear.

Indications: Erection disorders.

Contraindications: Hypersensitivity, nitrate therapy.

Use restrictions:

Anatomical deformity of the penis (angulation, cavernous fibrosis, Peyronie's disease), diseases predisposing to the development of priapism (multiple myeloma, sickle cell anemia, leukemia), increased bleeding tendency, exacerbation of gastric and duodenal ulcers, hereditary retinitis pigmentosa, violation liver function, incl. with cirrhosis, severe renal failure (Cl creatinine less than 30 ml / min), severe forms of arterial hypertension (BP above 170/110 mm Hg) and hypotension (BP below 90/50 mm Hg), anamnestic indications of myocardial infarction or stroke in the previous 6 months, life-threatening arrhythmias, heart failure, unstable angina, concomitant use of drugs that inhibit CYP3A4

Use with caution:

Before starting treatment to diagnose erectile dysfunction, determine its possible causes and select adequate treatment methods, it is necessary to collect a complete history and conduct a thorough urological and general clinical examination, especially in patients with concomitant cardiovascular diseases, for whom increased sexual activity is undesirable (for example, with severe forms of coronary artery disease and arterial hypertension). In patients over 65 years of age, with hepatic and severe renal insufficiency (Cl creatinine less than 30 ml / min), as well as with the simultaneous use of cytochrome P450 3A4 inhibitors (erythromycin, ketoconazole, itraconazole, saquinavir, etc.), the initial dose is 25 mg. While taking ritonavir, the maximum single dose should not exceed 25 mg within 48 hours. There are post-marketing reports of rare cases of erections lasting more than 4 hours and priapism requiring immediate medical attention to avoid damage to the penile tissue and irreversible impotence.

The safety of sildenafil when taken concomitantly with other drugs for the treatment of erectile dysfunction has not been studied, and concomitant use is not recommended.

Sildenafil is not indicated for use in neonates, children or women.

Side effects:

Side effects of sildenafil, observed in placebo-controlled trials and noted in \geq 2% of patients taking sildenafil, with a frequency greater than placebo (in parentheses is the % occurrence in the placebo group):

headache 16% (4%), dizziness 2% (1%), flushing 10% (1%), blurred vision (changes in color perception, increased sensitivity to light, blurred vision) 3% (0%), nasal congestion 4% (2%), diarrhea 3% (1%), urinary tract infections 3% (2%), skin rash 2% (1%).

Interaction:

A single dose of antacids (magnesium hydroxide / aluminum hydroxide) simultaneously with sildenafil does not affect its bioavailability. Sildenafil enhances the hypotensive effect of nitrates (simultaneous administration is contraindicated) and the antiaggregatory effect of sodium nitroprusside. When taken simultaneously with acetylsalicylic acid (150 mg), Sildenafil does not increase bleeding time. CYP3A4 inhibitors (cimetidine, ketoconazole, itraconazole, erythromycin, etc.) increase the concentration of sildenafil in plasma (in particular, cimetidine at a dose of 800 mg - by 56%, when taking sildenafil at a dose of 50 mg) and reduce its excretion. With a single dose of 100 mg of sildenafil against the background of an equilibrium concentration of erythromycin (500 mg twice a day for 5 days), the AUC of sildenafil increases by 182%, against the background of an equilibrium concentration of saquinavir (1200 mg 3 times a day), Cmax of sildenafil increases by 140%, AUC - by 210%. A single dose of 100 mg of sildenafil against the background of an equilibrium concentration of ritonavir, a potent inhibitor of cytochrome P450 (400 mg 2 times a day), leads to a 4-fold (300%) increase in Cmax and an 11-fold (1000%) increase in AUC of sildenafil. Sildenafil does not affect the pharmacokinetics of ritonavir and saquinavir. Inhibitors of CYP2C9 (tolbutamide, warfarin), CYP2D6 (selective serotonin reuptake inhibitors, tricyclic antidepressants), thiazides and thiazide-like diuretics, loop and potassiumsparing diuretics, ACE inhibitors, calcium antagonists, beta-blockers and cytochrome P450 inducers (rifampicin, barbiturates) do not influence on the pharmacokinetics of sildenafil. It is assumed that while taking sildenafil with CYP3A4 inducers (rifampicin, etc.), its plasma concentration will decrease. The AUC of the active metabolite of sildenafil increases by 62% when taking loop and potassium-sparing diuretics and by 102% when taking non-specific betablockers (the clinical significance of these effects has not been determined). There were no signs of interaction with amlodipine (5 and 10 mg): the average additional decrease in blood pressure in the supine position (SBP by 8 mm Hg, DBP by 7 mm Hg) is comparable to that when taking sildenafil alone in healthy volunteers. Sildenafil does not enhance the hypotensive effect of alcohol in healthy volunteers at blood alcohol concentrations up to 80 mg/dL.

Dosing and Administration:

Sildenafil is taken approximately 1 hour before sexual intercourse, 50 mg. Based on efficacy and tolerability, the dose may be increased to 100 mg or reduced to 25 mg. The maximum daily dose is 100 mg, the maximum recommended frequency of administration is 1 time per day.

Overdose:

Symptoms: in studies on healthy volunteers with a single dose of up to 800 mg of Sildenafil, an increase in the severity of side effects was noted.

Treatment: symptomatic. Dialysis is ineffective due to the high degree of binding of Sildenafil and its metabolite to plasma proteins.

Manufacturer:

Sildenafil-SZ: Severnaya Zvezda (Russia) Viagra: Pfizer, Fareva Amboise (France) Sildenafil Vertex: Vertex Pharma (Russia) Dynamico: Pliva Hrvatska (Croatia)

Vizarsin : KRKA (Slovenia) Maxigra : Polpharma (Poland)

Sildenafil Renewal: Renewal (Russia)

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.