EFFICACY OF TADALAFIL 5MG TREATMENT ON THE PREMATURE EJACULATION AND ERECTILE DYSFUNCTION

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Pharmaceutical form: coated tablets Contents: active substance: tadalafil - 20 mg. excipients: lactose, corn starch, sodium lauryl sulfate, isopropyl alcohol, povidone K-30, Aerosil, talc, croscarmellose sodium, magnesium stearate.

Excipients in the composition of the shell: hypromellose, dichloromethane, isopropyl alcohol, titanium dioxide, propylene glycol, yellow iron oxide, purified water.

Description: brownish-yellow, oval-shaped, biconvex, film-coated tablets with "E20" written on one side.

Pharmacotherapeutic group: Means for coordination of potency.

ATX code: G04BE

Pharmacological properties A drug used to treat erectile dysfunction. It is an irreversible selective inhibitor of cyclic guanosine monophosphate (sGMF) specific phosphodiesterase type 5 (FDE-5). When sexual arousal induces local nitric oxide release, inhibition of FDE-5 by tadalafil leads to increased levels of sGMF in the penile pore. This causes the smooth muscles in the arteries to relax and blood to flow to the penile tissue, causing an erection. Tadalafil has no effect in the absence of sexual stimulation.

In vitro studies have shown that tadalafil is a selective inhibitor of FDE-5. FDE-5 enzyme was detected in the smooth muscles of the porous body, smooth muscles of the blood vessels of internal organs, skeletal muscles, platelets, kidneys, lungs, brain.

The effect of tadalafil on FDE-5 is more active than on other phosphodiesterases. The activity of tadalafil against FDE-5 is 10,000 times higher than that of FDE-1, FDE-2,

FDE-4, FDE-7, which are found in the heart, brain, blood vessels, liver, leukocytes, skeletal muscles and other organs. Tadalafil blocks FDE-5, which is 10,000 times more active than the FDE-3 enzyme found in the heart and blood vessels. The selectivity of the drug over FDE-5 over FDE-3 is important because FDE-3 is an enzyme involved in the contraction of the heart muscle. In addition, the activity of tadalafil FDE-5 is about 700 times higher than that of FDE-6, which is detected in the retina and is responsible for the transmission of light.

Tadalafil is also 9000 times more potent against FDE-5 than FDE-8, FDE-9, and FDE-10, and 14 times more potent against FDE-5 than FDE-11.

Tadalafil improves the chances of having an erection and effective sexual intercourse.

The drug acts for 36 hours. The effect of the drug is manifested 16 minutes after taking the drug in case of sexual arousal.

Tadalafil lowers systolic and diastolic blood pressure (AB) in healthy subjects in the supine position (the mean maximal decrease in AB is 1.6/0.8 mmHg, respectively) and in the standing position (AB average maximum decrease is 0.2/4.6 mm.cm.sup.) does not call for a reliable change compared to placebo. Tadalafil does not cause a reliable change in heart rate.

Tadalafil does not cause a change in color separation (blue/green), which is explained by its low affinity for FDE-6. In addition, no effect of tadalafil on visual acuity, electroretinogram, intraocular pressure and pupil size is observed.

Several studies have been conducted to evaluate the effects of daily tadalafil on spermatogenesis. In no study, adverse effects of the drug on the morphology and motility of spermatozoa were observed. In one of the studies, a decrease in the average concentration of spermatozoa was found compared to placebo. A decrease in the concentration of spermatozoa was associated with a higher frequency of ejaculation. In addition, tadalafil did not cause adverse changes in the amount of testosterone, luteinizing hormone and follicle-stimulating hormone in blood plasma compared to placebo.

Adults (men) take Tadalit inside regardless of food. The recommended dose is 20 mg before anticipated sexual activity. The drug can be taken 16 minutes before sexual activity. The effectiveness of tadalafil is maintained for up to 36 hours after taking a dose of the drug. The recommended maximum number of receptions is 1 per day.

Side effects Adverse reactions associated with taking tadalafil are usually mild or moderate in severity, transient, and diminish with continued use of the drug.

The following indicators of the frequency of side effects are defined as follows: very often (>1/10), often (>1/100 to <1/10), not often (>1/1000 to <1/100), rarely (>1/10000 to <1/1000), very rarely (<1/10000).

From the cardiovascular system: infrequently - palpitations, tachycardia, decrease in AB (in patients who have already taken hypotensive drugs), increase in AB; in rare cases - myocardial infarction; unknown - unstable angina pectoris, death due to sudden cardiac arrest.

From the nervous system: very often - headache; often - dizziness; in rare cases - loss of appetite, migraine, transient ischemic attack, stroke.

From the organs of vision: infrequently - blurred vision; in rare cases - loss of field of vision; not known - non-arterial anterior ischemic optic neuropathy of the optic nerve, retinal vein occlusion.

In short, sexual activity poses a potential risk for patients with cardiovascular disease. Therefore, treatment of erectile dysfunction, including the drug Tadalit, cannot be carried out in men with such heart diseases who are not recommended for sexual activity.

There are reports of the development of priapism with the use of FDE-5 inhibitors, including tadalafil. Patients should be warned to seek immediate medical attention when an erection lasting 4 hours or more develops. Failure to treat priapism on time can damage the tissues of the penis, resulting in irreversible impotence.

The safety and effectiveness of using Tadalit along with other types of erectile dysfunction treatment have not been studied. Therefore, it is not recommended to use such complexes.

Tadalafil (like other FDE-5 inhibitors) has systemic vasodilator properties, which may cause a transient decrease in AB. Before prescribing Tadalit, doctors should carefully consider the possibility that patients with cardiovascular diseases may experience side effects due to the drug's vasodilating effect.

Nonarterial anterior ischemic optic neuropathy (NAOION) is a cause of visual impairment, including complete vision loss. There are very few reports of the development of time-dependent NAOION with the administration of FDE-5 inhibitors. Currently, it is not possible to determine whether there is an indirect relationship between the development of NAOION and the reception of FDE-5 inhibitors or other factors. Physicians should advise patients to stop taking tadalafil and seek medical attention in the event of sudden loss of vision. Also, doctors should explain to patients that there is a high risk of recurrent NAO in people who have undergone NAO.

References

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