

Vigorex™

Sildenafil

COMPOSITION

Vigorex™ 25 Tablet: Each film coated tablet contains Sildenafil 25 mg as Sildenafil Citrate BP.

Vigorex™ 50 Tablet: Each film coated tablet contains Sildenafil 50 mg as Sildenafil Citrate BP.

Vigorex™ 100 Tablet: Each film coated tablet contains Sildenafil 100 mg as Sildenafil Citrate BP.

PHARMACOLOGY

Vigorex™ belongs to a group of medicines called phosphodiesterase type-5 (PDE-5) inhibitors. It works by helping to relax the blood vessels of penis, allowing blood to flow into penis. The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. NO then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood. When sexual stimulation causes local release of NO, inhibition of PDE-5 by sildenafil causes increased levels of cGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum. Sildenafil at recommended doses has no effect in the absence of sexual stimulation.

INDICATION

Vigorex™ is indicated for the treatment of Erectile Dysfunction.

DOSAGE & ADMINISTRATION

The usual starting dose of **Vigorex™** is 50 mg once daily. It should be taken before 30-40 minutes of intercourse. Depending on effectiveness and tolerance; the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. The maximum dosing frequency is once per day. Some factors are associated with increased plasma levels of sildenafil: age>65, hepatic impairment, severe renal impairment and concomitant use of ketoconazole, itraconazole, erythromycin. Since higher plasma levels may increase both the efficacy and incidence of adverse events, a starting dose of 25 mg should be considered in these patients. **Vigorex™** may take longer time to work if you take it with a heavy meal.

CONTRAINDICATIONS

Sildenafil was shown to potentiate the hypotensive effects of nitrates and its administration to patients who are using organic nitrates, either regularly and or intermittently, in any form is therefore contraindicated.

SIDE EFFECTS

Like all medicines, Sildenafil can cause side effects although not everybody gets them. The side effects reported in association with the use of Sildenafil are usually mild to moderate and of a short duration. All medicines including Sildenafil can cause allergic reactions. Contact with doctors immediately if experiences any of the following symptoms after taking Sildenafil: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat. Common side effect includes headache, facial flushing, indigestion, effects on vision, light sensitivity, blurred vision or reduced, stuffy nose and dizziness. Uncommon side effect includes vomiting, skin rash, bleeding at the back of the eye, red eyes, eye pain, double vision, abnormal sensation in the eye, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain & feeling tired.

WARNINGS

In patients with preexisting cardiovascular disease, there is a potential risk in sexual activity. Sildenafil should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status. Sildenafil has systemic vasodilatory properties. Patients with left ventricular outflow obstruction (e.g. aortic stenosis, idiopathic hypertrophic subaortic stenosis) and those with severely impaired autonomic control of blood can be particularly sensitive to the actions of vasodilators including Sildenafil. There is no controlled clinical data on the safety or efficacy of Sildenafil in Patients who have suffered from a myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months. Caution should be taken in patients with resting hypotension, cardiac failure or coronary artery disease causing unstable angina, retinitis pigmentosa. Prolonged erection greater than 4 hours and priapism (painful erections greater than 6 hours in duration) have been reported infrequently since market approval of Sildenafil. In this situation, patient should seek immediate medical assistance.

PRECAUTION

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription. Sildenafil tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell the healthcare professional treating your condition that you have taken Sildenafil and if you did, do not take Sildenafil with other medicines unless your doctor tells you can. You should not take Sildenafil if you are taking medicines called nitrates as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or chest pain). You should not take Sildenafil if you are using any of the drugs known as nitric oxide donors such as amyl nitrite as the combination may also lead to potentially dangerous decrease in your blood pressure. If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Sildenafil. Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildenafil with alpha-blocker. This is most likely to occur within 4 hours after taking Sildenafil. In order to reduce the likelihood of these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil. Your doctor may start you on a lower dose (25 mg) of Sildenafil if you have hypotension (avoid if systolic blood pressure below 90 mmHg), recent stroke, unstable angina & myocardial infarction. Drinking alcohol can temporarily impair your ability to get an erection, to get the maximum benefit from your medicine; you are advised not to drink excessive amounts of alcohol before taking Sildenafil.

OVER DOSAGE

In studies with healthy volunteers of single doses up to 800 mg, adverse events were similar to those seen at lower doses but incidence rates and severities were increased. In cases of overdose, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma proteins and it is not eliminated in the urine.

PREGNANCY, LACTATION AND PAEDIATRIC USE

Vigorex™ is not indicated for use in newborns, children & women.

STORAGE

Store below 30° C. Protect from light. Keep out of reach of children.

HOW SUPPLIED

Vigorex™ 25 Tablet: Each box contains 8 tablets.

Vigorex™ 50 Tablet: Each box contains 8 tablets.

Vigorex™ 100 Tablet: Each box contains 8 tablets.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH