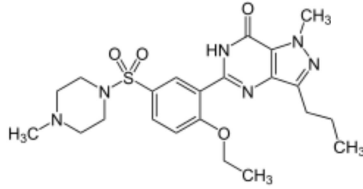


# Sildenafil

Sildenafil Tablet, USP



DIN 00496545

100 mg

30 Capsule, Square container

**Systematic name: 1-[4-ethoxy-3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)phenylsulfonyl]-4-methylpiperazine**

## DESCRIPTION

Sildenafil, also known under the name of Viagra, is a phosphodiesterase type 5 inhibitor. Phosphodiesterase type 5 is used in the treatment of erectile dysfunction (impotence). It helps to produce and maintain a sufficient state of erection to take part in sexual activities by increasing the inflow of blood inside the penis of a man sexually aroused at the time of taking the medication. It should be taken only after sexual stimulation, yet it does not increase sexual desire. It is also used as a treatment for pulmonary hypertension.

## COMPOSITION

Each capsule contains: Medicinal ingredients. Sildenafil 100 mg Non-medicinal ingredients. Dextrose, microcrystalline cellulose.

## CLINICAL PHARMACOLOGY

Sildenafil enhances the effect of Nitric oxide (NO) in the corpus cavernosum of the penis binds to guanylate cyclase receptors, which results in increased levels of cGMP, leading to smooth muscle relaxation (vasodilation) of the intimal cushions of the helicine arteries. This smooth muscle relaxation leads to vasodilation and increases inflow of blood into the spongy tissue of the penis, causing an erection.

## INDICATIONS

Sildenafil is used to treat erectile dysfunction and pulmonary arterial hypertension.

## CONTRAINDICATIONS

Sildenafil is contraindicated in patients taking nitric oxide, organic nitrites and nitrates or drugs that contain nitrates, as there is a risk of life-threatening hypotension. Taking nitrates in any form whatsoever (oral, sublingual, transdermal, inhalation), continuous treatment or as needed, is absolutely contraindicated.

## ADVERSE REACTIONS

Common side effects of Sildenafil include facial flushing, headaches, stomach pain, nasal congestion, nausea, diarrhea, an inability to differentiate between the colors green and blue, a loss of hearing, and ringing in the ears and dizziness.

### **MECHANISM OF ACTION**

The physiologic mechanism of erection of the penis involves a 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), allowing smooth muscle relaxation in the corpus cavernosum and inflow of blood.

Sildenafil enhances the effect of NO by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of cGMP in the corpus cavernosum. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum. When sexual stimulation causes local release of NO, inhibition of PDE5 by sildenafil increases 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.

### **STORAGE INSTRUCTIONS**

Store sildenafil at room temperature, between 15-30 degrees Celsius (59° to 86° F), in a tightly closed, light-resistant container. Keep out of reach of children.