

# Vegara<sup>®</sup>

## Sildenafil

### DESCRIPTION

Vegara<sup>®</sup> is a preparation of sildenafil (as citrate form). Sildenafil is an oral therapy for erectile dysfunction. 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. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum, but enhances the effect of nitric oxide (NO) by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of cGMP in the corpus cavernosum results in 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.

### INDICATIONS

Indicated for the treatment of erectile dysfunction.

### DOSAGE AND ADMINISTRATION

For most patients, the recommended dose of Vegara<sup>®</sup> is 50 mg taken, as needed, approximately 1 hour before sexual activity. However, Vegara<sup>®</sup> may be taken anywhere from 4 hours to 0.5 hour before sexual activity. Based on effectiveness and toleration, the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. The maximum recommended dosing frequency is once per day.

Age >65, hepatic impairment and severe renal impairment are associated with increased plasma levels of sildenafil. A starting oral dose of 25 mg should be considered in those patients.

Need to avoid high-fat meals 2 hours before taking Sildenafil.

### 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.

Hypersensitivity to active component.

### WARNINGS & PRECAUTIONS

There is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments for erectile dysfunction, including Sildenafil, should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.

Caution is advised when Sildenafil co-administered with alpha-blockers. Sildenafil and alpha-adrenergic blocking agents are both vasodilators with blood pressure lowering effects.

The concomitant administration of the protease inhibitor ritonavir substantially increases serum concentrations of sildenafil (11-fold increase in AUC). If Sildenafil is prescribed to patients taking ritonavir, caution should be used.

In the event of an erection that persists longer than 4 hours, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result.

### USE IN PREGNANCY AND LACTATION

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

### SIDE EFFECTS

Headache, Flushing, Dyspepsia.

### PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

### PACKAGING

**Vegara<sup>®</sup>50** tablet: Each box contains 2x4 tablets. Each tablet contains Sildenafil Citrate BP equivalent to Sildenafil 50 mg.

**Vegara<sup>®</sup>100** tablet: Each box contains 1x4 tablets. Each tablet contains Sildenafil Citrate BP equivalent to Sildenafil 100 mg.

 Manufactured by  
**EURO Pharma Ltd.**  
*In Pursuit of Excellence*  
Dhaka, Bangladesh

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