



## COMPOSITION

Vardamate™ 10 Tablet: Each tablet contains Vardenafil Hydrochloride Trihydrate BP equivalent to Vardenafil 10 mg.

Vardamate™ 20 Tablet: Each tablet contains Vardenafil Hydrochloride Trihydrate BP equivalent to Vardenafil 20 mg.

## PHARMACOLOGY

Does not directly cause penile erections, but affects the response to sexual stimulation. 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 and inflow of blood to the corpus cavernosum. Vardenafil enhances the effect of NO by inhibiting phosphodiesterase type 5 (PDE-5), which is responsible for degradation of cGMP in the corpus cavernosum; when sexual stimulation causes local release of NO, inhibition of PDE-5 by Vardenafil causes increased levels of cGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum; at recommended doses, it has no effect in the absence of sexual stimulation.

## INDICATION

Vardamate™ is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction.

## DOSAGE AND ADMINISTRATION

Initial dose: 10 mg orally once a day, as needed, approximately 60 minutes before sexual activity. Increase to 20 mg or decrease to 5 mg based on efficacy and tolerability. Vardamate™ can be taken with or without food.

Maximum dose: 20 mg once a day

Usual Geriatric Dose for Erectile Dysfunction (65 years or older): 5 mg orally once a day, as needed, approximately 60 minutes before sexual activity

Hepatic & Renal impairment: For patients with mild hepatic and renal impairment, no dose adjustment of Vardenafil is required.

## Paediatric Population

Vardamate™ is not indicated for individuals below 18 years of age.

## SIDE EFFECTS

The most common side effects with Vardenafil are headache, flushing, stuffy or runny nose, indigestion, upset stomach, or dizziness. These side effects usually go away after a few hours.

## CONTRAINDICATIONS

Administration of Vardenafil with nitrates (either regularly and/or intermittently) and nitric oxide donors is contraindicated

## WARNINGS AND PRECAUTIONS

Physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Therefore, treatment for erectile dysfunction, including Vardenafil, should not be used in men for whom sexual activity is not recommended because of their underlying cardiovascular status.

There are no controlled clinical data on the safety or efficacy of Vardenafil in the following patients; and therefore its use is not recommended until further information is available: unstable angina; resting systolic blood pressure of 170/110 mmHg; recent history of stroke, life-threatening arrhythmia, or myocardial infarction (within the last 6 months); severe cardiac failure.

## USE IN PREGNANCY AND LACTATION

There are no studies of Vardenafil use in pregnant women. It is not known if Vardenafil is excreted in human breast milk.

## OVERDOSAGE

The maximum dose of Vardenafil for which human data are available is a single 120 mg dose administered to healthy male volunteers. The majority of these subjects experienced reversible back pain/myalgia and/or "abnormal vision." Single doses up to 80 mg vardenafil and multiple doses up to 40 mg vardenafil administered once daily over 4 weeks were tolerated without producing serious adverse side effects.

## STORAGE

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

## HOW SUPPLIED

Vardamate™ 10 Tablet: Each box contains 10 Tablets in blister pack.

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Manufactured by



**SQUARE**  
**PHARMACEUTICALS LTD.**

Salgaria, Pabna, Bangladesh

TM-Trade Mark