



## Levitra<sup>®</sup> (vardenafil)

### Background

#### Overview

Levitra<sup>®</sup> (vardenafil HCl) is a prescription-only oral medication for the treatment of erectile dysfunction (ED). Levitra<sup>®</sup> belongs to a class of products called phosphodiesterase type 5 (PDE-5) inhibitors. PDE-5 inhibitors typically work by blocking an enzyme to enhance or prolong the erectile response following sexual stimulation.

#### Impact of ED on Men's Quality of Life

Research has shown a link between ED and depression. For the individual patient, ED may result in loss of self-esteem, poor self-image and disruption of interpersonal relationships.<sup>1</sup>

According to the largest ever study of men's attitudes to life events and sexuality, 25% of men with ED reported depression and anxiety.<sup>2</sup>

#### Levitra<sup>®</sup> Improves Quality of Life

Levitra<sup>®</sup> is the only drug of its kind that has been shown in randomized, controlled clinical studies to extend duration of erection as measured by a stopwatch method 2-3x over placebo<sup>3,4</sup>. Levitra<sup>®</sup> has been proven to significantly improve the quality of life of men with ED and their partners.<sup>5</sup>

The COUPLES study compared patient and partner satisfaction with Levitra<sup>®</sup> compared to placebo in the treatment of ED.<sup>5</sup> Couples agreed that Levitra<sup>®</sup> provided significantly greater sexual satisfaction versus placebo and that satisfaction was achieved not only by the man, but also by his partner.



### **Rapid Onset of Levitra®**

Levitra® has a fast onset of action. Study data demonstrated that Levitra® 10 mg works quickly and can produce an erection upon sexual stimulation as early as 10 minutes after intake of the medication,<sup>6</sup> in the majority of men this can be within 15 minutes.<sup>7</sup>

### **Association of ED and Underlying Conditions**

In many men, ED is caused by underlying conditions such as diabetes, heart disease and / or abdominal obesity and their impaired sexual function is an early indicator of the presence of these conditions.<sup>8</sup> Health issues like diabetes, high cholesterol and abdominal obesity are also associated with testosterone deficiency syndrome,<sup>9</sup> which may also be a factor in some men's ED.

Therefore in men with ED there is often a higher prevalence of underlying conditions: 64% of men with ED report at least one or more of the following conditions: hypertension, chronic heart disease / angina, high cholesterol, diabetes or depression.<sup>10</sup> Many men do not know that they have one or more of these conditions.

### **Management of ED in Men with Underlying Conditions**

When men with ED present to a physician, it is important for their well-being and the health of their personal relationships that ED is treated immediately. Although it is a common condition, evidence shows that ED sufferers often do not seek treatment,<sup>11</sup> despite the availability of effective treatments such as Levitra®.

It is important that the causes of the ED are explored and this includes testing whether the man is testosterone deficient. Treating low testosterone can often improve the components of the Metabolic Syndrome<sup>1213</sup> a condition a condition involving a cluster of inter-related factors, including, high cholesterol, high blood pressure, diabetes or insulin resistance and abdominal obesity<sup>14</sup>, and alleviates also the loss of muscle mass, fatigue<sup>1516</sup> and depression.<sup>171819</sup>



### **Treating ED with Levitra<sup>®</sup> in Men with Underlying Conditions**

Levitra<sup>®</sup> is a highly potent PDE-5 inhibitor for men with ED who also have underlying conditions.

A retrospective analysis of 13 studies with more than 4,300 men with ED and underlying conditions indicated that Levitra<sup>®</sup> improves erectile function, penetration and successful intercourse rates irrespective of the underlying condition. In addition, Levitra<sup>®</sup> was efficacious and safe when taken with commonly used medications for the treatment of underlying conditions such as blood pressure lowering drugs.<sup>20</sup>

Other results demonstrate that 87% of men treated with Levitra<sup>®</sup> achieved successful penetration on the first attempt<sup>21</sup> and were subsequently successful 85% of the time<sup>22</sup>.

### **Tolerability and Safety**

Levitra<sup>®</sup> has been clinically shown to be well tolerated. In placebo-controlled clinical trials, adverse events were generally transient and mild to moderate in intensity.<sup>23,24,25</sup> The most common adverse events reported for Levitra<sup>®</sup> were headache, flushing, dyspepsia and nasal congestion.

### **Contraindications**

Levitra<sup>®</sup> is contraindicated in men taking nitrates and nitric oxide donors including amyl nitrates, certain HIV protease inhibitors such as ritonavir and indinavir. In addition, Levitra must not be used by patients who have loss of vision in one eye because of non-arteritic anterior ischemic optic neuropathy (NAION).

### **Bayer Schering Pharma**

Bayer Schering Pharma is a worldwide leading pharmaceutical company. Its research and business activities are focused on the following areas: diagnostic



imaging, general medicine, specialty medicine and women's healthcare. It also has a dedicated Men's Healthcare Group that brings together a rich heritage in innovative men's health products and a strong commitment to meeting patients' needs. With new ideas and innovative products, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life of patients.

For more information about ED, visit [www.bayerscheringpharma.de](http://www.bayerscheringpharma.de)

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