

Facts About Benign Prostatic Hyperplasia (BPH)

About BPH	Benign Prostatic Hyperplasia, or BPH, is characterized by a non-cancerous enlarged prostate, which causes urinary obstruction, resulting in urination problems. Eventually, urine remains in the bladder, which can lead to poor bladder emptying and complications.
Affected Population	BPH is the number one reason patients visit a urologist and the fourth most prevalent condition among men over age 50. In the United States, BPH affects more than half of men age 50 and older and close to 90 percent of men by the age of 80. As the population ages, the number of men with BPH is expected to increase.
Symptoms	<p>Symptoms of BPH are caused by an obstruction of the urethra (the tube connecting the bladder to the outside) and a gradual loss of bladder function. As a result, the bladder may not completely empty during urination.</p> <p>The most common symptoms of BPH include:</p> <ul style="list-style-type: none"> • Increased urinary urgency, leakage or dribbling • Frequent urination at night (nocturia) • Hesitant, interrupted or weak stream
Healthcare Costs	<p>Every year, BPH accounts for an estimated:</p> <ul style="list-style-type: none"> • 4.5 million physicians' visits • \$1.1 billion in direct medical service costs • \$26 billion in annual healthcare costs
Unmet Medical Need	<p>There are a number of treatments for men with BPH, including medications such as alpha blockers and 5-alpha reductase inhibitors, and surgery. Still, there remain unmet patient needs and widespread numbers of undiagnosed patients – as many as 15 million.</p> <p>Recently, the U.S. Food and Drug Administration (FDA) approved RAPAFLORTM (silodosin), a new treatment for the signs and symptoms of BPH. This selective alpha-1 adrenergic receptor antagonist provides patients managing their BPH with strong efficacy and a favorable safety profile, and clinical studies have shown that RAPAFLOR does not cause any meaningful prolongation of the QT interval. QTc prolongation can cause cardiac arrhythmias, which can lead to cardiac events.</p> <p>RAPAFLOR was well tolerated in clinical trials with minimal effects on the cardiovascular system. The most common drug-related side effect was retrograde ejaculation (orgasm with reduced semen), a direct reflection of the product's selective binding properties. Rates of discontinuing therapy due to retrograde ejaculation were low. The second most commonly-reported adverse event was dizziness. The incidence of treatment-related dizziness was low and only slightly higher among RAPAFLOR than placebo-treated patients.</p>