

# BPH

## ■ What Is It and ■ How It Can ■ Affect Your Life?

**If you're a man past middle age,** there's a good chance that you have or may develop a condition known as benign prostatic hyperplasia (BPH). This noncancerous condition affects about 40% of men in their 50s, 60% of men in their 60s, and more than 80% of men in their 80s. About half of such men develop moderate to severe lower urinary tract symptoms (LUTS), which may interfere with sleep and normal daily activities, tend to worsen with advancing age, and can indicate either obstruction or irritation of the urinary tract.

Not all LUTS are due to BPH and not all men with BPH have LUTS, but even those who don't may develop other BPH-related problems that require treatment. There are, however, a number of treatment options for men with BPH—some of which may improve LUTS associated with other conditions as well.

### UNDERSTANDING BPH

The prostate gland is unique to men. It's responsible for secreting the major portion of ejaculatory fluid. Seated directly below the bladder and surrounding the urethra, the prostate continues to grow throughout life. As a man ages, the prostate may become so large that it presses on the bladder or urethra, causing problems with urination and, over time, damaging the bladder or kidney or contributing to the development of kidney stones.

When the prostate first starts to enlarge, the bladder muscle can usually push urine through the constricted urethra. As the narrowing continues, though, the bladder muscle may become thicker or weaken. This can cause the man to strain to empty his bladder or to feel an intense urge to urinate when the bladder is only partially full (urgency). A man with severe urgency may



Photo: Model in photo is being depicted for illustrative purposes only.

get up several times a night to urinate. Men with LUTS and BPH also have been found to be at greater risk for erectile dysfunction (ED), which means they find it difficult to have an erection or to maintain one long enough to have satisfactory sex. The more severe a man's LUTS, the more severe his ED tends to be.

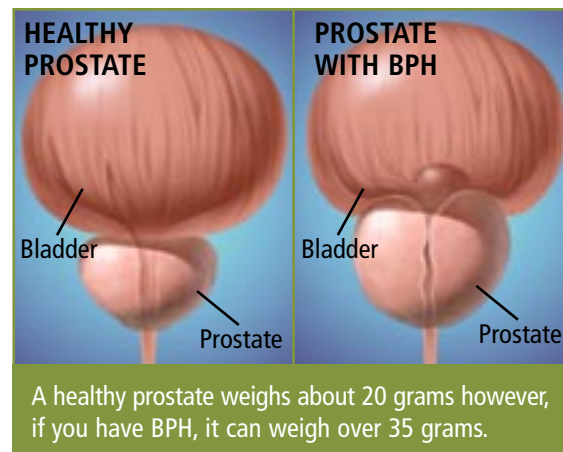
The connection between LUTS, BPH, and ED isn't entirely clear. In some cases, severe LUTS may represent circulatory abnormalities or changes in nervous system control of the lower urinary tract, which may similarly affect the penis and contribute to ED. Some evidence suggested from animal studies is that the enlarged prostate leads to biochemical changes in the pelvic region affecting the biological function of penile tissue required for erection, linking LUTS, BPH, and ED.

### WHEN TO SEE YOUR DOCTOR

If you have any bothersome LUTS or ED, see your doctor to find out whether the problems stem from BPH or something else.

### HOW BPH IS DIAGNOSED

Your doctor will probably start by taking a thorough medical history, which will include asking how much fluid you normally drink in a day and what medications you're currently taking. (Some drugs—such as certain bronchodilators, decongestants, and appetite suppressants—may bring on urinary symptoms.) You'll need to tell your doctor if you have a family history of coronary artery disease, hypertension, or diabetes—conditions that



complicate management of BPH.

Your physical exam will likely include a digital rectal exam, in which the doctor inserts a gloved, lubricated finger into your rectum to feel for any abnormalities. Your urine will be checked for blood, sugar, signs of infection, and depending on your symptoms, for cancer cells (to rule out bladder cancer). Your doctor may take a blood sample to check your level of prostate-specific antigen, a measurement that rises with prostate disorders. In addition, the speed of your urine flow after you've held your urine for some time and the volume of urine left in the bladder after you have voided may be measured. These measurements can help the doctor determine the extent of your urinary tract obstruction.

In assessing your symptoms, your doctor will likely use one of two well known aids: the "BPH Symptom Score Index" (see the box on page 5), which was developed by the American Urological Association (AUA) or the International Prostate Symptom Score (IPSS) developed by the World Health Organization. The IPSS is identical to the BPH Symptom Score Index except that, in addition to the seven multiple-choice questions about urinary symptoms, it contains an eighth about how bothersome you find the symptoms. Your answers to the questions can help your doctor determine the nature, frequency, and severity of your LUTS and how they may pertain to BPH.

Illustrations by: Craig Zuckerman

## AVAILABLE TREATMENTS FOR BPH

Type of treatment	Examples	How it works
<b>Medical</b>		
Alpha-adrenergic blocker	Cardura, Flomax, Hytrin, and Uroxatral	Relax smooth muscle cells in the prostate to relieve urinary obstruction caused by prostatic contraction
5 alpha-reductase inhibitor	Avodart and Proscar	Cause hormonal changes that shrink the prostate
<b>Minimally invasive procedures</b>		
	TUMT, TUNA	Use high temperatures to cause tissue destruction in the prostate
	VLAP	Uses laser energy to cause tissue destruction in the prostate
	TUVP	Uses laser energy to vaporize prostate tissue
	Stenting	Small metal supports are inserted into the urethra to keep it open
<b>Surgical</b>		
	TURP, prostatectomy	The inner portion of the prostate is removed—either through the urethra, using an endoscope (TURP) or open surgery (prostatectomy)
	TUIP	Reduces urethral constriction by cutting the prostate in one or two places

BPH = benign prostatic hypertrophy; TUMT = transurethral microwave therapy; TUNA = transurethral needle ablation; VLAP = visual laser ablation of the prostate; TUVP = transurethral vaporization of the prostate; TURP = transurethral resection of the prostate; TUIP = transurethral incision of the prostate.

## AMERICAN UROLOGICAL ASSOCIATION BPH SYMPTOM SCORE INDEX

To complete this self-test, simply check one answer for each question. Once you have answered all 7 questions, add up your total points to see your score.

	0 pt Not at all	1 pt Less than 1 time in 5	2 pt Less than half the time	3 pt About half the time	4 pt More than half the time	5 pt Almost always	Score
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?							
2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?							
3. Over the past month, how often have you stopped and started again several times when you urinated?							
4. Over the past month, how often have you found it difficult to postpone urination?							
5. Over the past month, how often have you had a weak urinary stream?							
6. Over the past month, how often have you had to push or strain to begin urination?							
7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?							
<b>Total symptom score</b>							

The possible total score ranges from 0 to 35 points with higher scores indicating more severe symptoms. Scores less than 7 are considered mild and generally do not warrant treatment.

If your symptoms are not severe and you have no signs of serious injury to your urinary tract, your doctor may suggest a period of regular symptom monitoring with no immediate treatment. If, however, you have symptoms that are moderate to severe, a significant family history of BPH-related problems, or serious urinary tract injury, then medical, minimally invasive, and surgical treatments are available (see box on page 4).

### MEDICAL THERAPIES

Among medical therapies used to treat BPH, alpha-adrenergic blockers tend to be used most. There are 4 alpha blocker drugs used to treat BPH: Cardura, Flomax, Hytrin, and Uroxatral.

Alpha blocker therapy is based on the idea that the LUTS associated with BPH are caused partly by obstruction resulting from the contraction of smooth muscle cells in the

prostate. The alpha blockers inhibit the process by which this contraction occurs and, thereby, relieve the obstruction. According to the 2006 update of the AUA Guideline on the Management of Benign Prostatic Hyperplasia, clinical studies show these drugs to be similarly effective in reducing LUTS, improving patients' BPH Symptom Score Index by 4 to 6 points on average.

The other drugs used to treat BPH are the 5 alpha-reductase inhibitors. Two are available: Avodart and Proscar. These drugs work by bringing about hormonal changes that actually shrink the prostate.

The AUA guideline recommends that these drugs be used only by men with clear signs of prostate enlargement, not simply LUTS. According to the AUA guideline, in men with substantially enlarged prostates, these drugs can increase urinary flow rate and lower both the

risk of acute urinary retention and the need for BPH-related surgery. In such men, they also can reduce LUTS, producing on average a three-point improvement in the BPH Symptom Score Index. They are, however, less effective in relieving LUTS than alpha blockers and ineffective against LUTS in patients without enlarged prostates.

### MINIMALLY INVASIVE PROCEDURES

The minimally invasive procedures used to treat BPH tend to be more effective than medical options, but carry greater risks. They include transurethral microwave therapy (TUMT), transurethral needle ablation (TUNA), visual laser ablation of the prostate (VLAP), transurethral vaporization of the prostate (TUVP), and stenting. These procedures may be performed within a

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doctor's office or in a hospital with a one-day stay. Either local anesthesia or intravenous sedation is required.

Heat treatments, such as TUMT and TUNA, use high temperatures to cause the prostate tissue to shrivel and become less tense. The result is that the obstructive mass of the prostate is reduced.

Similar to the heat treatments, VLAP uses laser energy to cause prostate tissue to shrivel and slough away, and TUVF uses laser energy to vaporize prostate tissue. Both procedures relieve prostatic urinary obstruction.

Some patients have metal stents inserted into the urethra to keep it open. It is unclear, however, whether stents are appropriate for men whose medical conditions permit other forms of treatment.

## SURGICAL TREATMENT

Surgery for BPH—transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), and prostatectomy—are the traditional and most effective but are the riskiest treatment options. All 3 require spinal or general anesthesia with at least a 1-night hospital stay.

With TURP, the inner portion of the prostate is cut out through the urethra using an endoscope, whereas TUIP reduces urethral constriction by inserting an instrument through the urethra to make 1 or 2 cuts in the prostate. The most radical option, prostatectomy, removes the inner portion of the prostate through open surgery. Usually, prostatectomy is reserved for patients with a prostate volume greater than 80 g.

## WEIGHING YOUR OPTIONS

When discussing possible treatments with your doctor, weigh the severity of your symptoms against the likelihood that treatment will noticeably reduce your symptoms. Be sure to consider the potential risks as well as the unwanted effects that may occur and the length of time they may last. □

## PATIENT SUMMARY OF INFORMATION ABOUT

# VIAGRA®

(sildenafil citrate) tablets

**This summary contains important information about VIAGRA®.** It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking VIAGRA. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about VIAGRA.

This medicine can help many men when it is used as prescribed by their doctors. However, VIAGRA is not for everyone. It is intended for use only by men who have a condition called erectile dysfunction. **VIAGRA must never be used by men who are taking medicines that contain nitrates of any kind, at any time. This includes nitroglycerin. If you take VIAGRA with any nitrate medicine your blood pressure could suddenly drop to an unsafe or life threatening level.**

### • What Is VIAGRA?

VIAGRA is a pill used to treat erectile dysfunction (impotence) in men. It can help many men who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated).

You will not get an erection just by taking this medicine. VIAGRA helps a man with erectile dysfunction get an erection only when he is sexually excited.

### • How Sex Affects the Body

When a man is sexually excited, the penis rapidly fills with more blood than usual. The penis then expands and hardens. This is called an erection. After the man is done having sex, this extra blood flows out of the penis back into the body. The erection goes away. If an erection lasts for a long time (more than 6 hours), it can permanently damage your penis. You should call a doctor immediately if you ever have a prolonged erection that lasts more than 4 hours.

Some conditions and medicines interfere with this natural erection process. The penis cannot fill with enough blood. The man cannot have an erection. This is called erectile dysfunction if it becomes a frequent problem.

During sex, your heart works harder. Therefore sexual activity may not be advisable for people who have heart problems. Before you start any treatment for erectile dysfunction, ask your doctor if your heart is healthy enough to handle the extra strain of having sex. If you have chest pains, dizziness or nausea during sex, stop having sex and immediately tell your doctor you have had this problem.

### • How VIAGRA Works

VIAGRA enables many men with erectile dysfunction to respond to sexual stimulation. When a man is sexually excited, VIAGRA helps the penis fill with enough blood to cause an erection. After sex is over, the erection goes away.

### • VIAGRA Is Not for Everyone

As noted above (*How Sex Affects the Body*), ask your doctor if your heart is healthy enough for sexual activity.

**If you take any medicines that contain nitrates – either regularly or as needed – you should never take VIAGRA.** If you take VIAGRA with any nitrate medicine or recreational drug containing nitrates, your blood pressure could suddenly drop to an unsafe level. You could get dizzy, faint, or even have a heart attack or stroke. Nitrates are found in many prescription medicines that are used to treat angina (chest pain due to heart disease) such as:

- nitroglycerin (sprays, ointments, skin patches or pastes, and tablets that are swallowed or dissolved in the mouth)
- isosorbide mononitrate and isosorbide dinitrate (tablets that are swallowed, chewed, or dissolved in the mouth)

Nitrates are also found in recreational drugs such as amyl nitrate or nitrite ("poppers"). If you are not sure if any of your medicines contain nitrates, or if you do not understand what nitrates are, ask your doctor or pharmacist.

VIAGRA is only for patients with erectile dysfunction. VIAGRA is not for newborns, children, or women. Do not let anyone else take your VIAGRA. VIAGRA must be used only under a doctor's supervision.

### • What VIAGRA Does Not Do

- VIAGRA does not cure erectile dysfunction. It is a treatment for erectile dysfunction.
- VIAGRA does not protect you or your partner from getting sexually transmitted diseases, including HIV — the virus that causes AIDS.
- VIAGRA is not a hormone or an aphrodisiac.

### • What To Tell Your Doctor Before You Begin VIAGRA

Only your doctor can decide if VIAGRA is right for you. VIAGRA can cause mild, temporary lowering of your blood pressure. You will need to have a thorough medical exam to diagnose your erectile dysfunction and to find out if you can safely take VIAGRA alone or with your other medicines. Your doctor should determine if your heart is healthy enough to handle the extra strain of having sex.

Be sure to tell your doctor if you:

- have ever had any heart problems (e.g., angina, chest pain, heart failure, irregular heart beats, heart attack or narrowing of the aortic valve)
- have ever had a stroke
- have low or high blood pressure
- have ever had severe vision loss
- have a rare inherited eye disease called retinitis pigmentosa
- have ever had any kidney problems
- have ever had any liver problems
- have ever had any blood problems, including sickle cell anemia or leukemia
- are allergic to sildenafil or any of the other ingredients of VIAGRA tablets

- have a deformed penis, Peyronie's disease, or ever had an erection that lasted more than 4 hours
- have stomach ulcers or any types of bleeding problems
- are taking any other medicines

### • VIAGRA and Other Medicines

Some medicines can change the way VIAGRA works. Tell your doctor about **any medicines** you are taking. Do not start or stop taking any medicines before checking with your doctor or pharmacist. This includes prescription and nonprescription medicines or remedies:

- Remember, VIAGRA should never be used with medicines that contain nitrates (see *VIAGRA Is Not for Everyone*).
- If you are taking alpha-blocker therapy for the treatment of high blood pressure or prostate problems, you should not take a dose of greater than 25 mg of VIAGRA at the same time (within 4 hours) as you take your dose of alpha-blocker.
- If you are taking a protease inhibitor, your dose may be adjusted (please see *Finding the Right Dose for You*).
- VIAGRA should not be used with any other medical treatments that cause erections. These treatments include pills, medicines that are injected or inserted into the penis, implants or vacuum pumps.

### • Finding the Right Dose for You

VIAGRA comes in different doses (25 mg, 50 mg and 100 mg). If you do not get the results you expect, talk with your doctor. You and your doctor can determine the dose that works best for you.

- Do not take more VIAGRA than your doctor prescribes.
- If you think you need a larger dose of VIAGRA, check with your doctor.
- VIAGRA should not be taken more than once a day.

If you are older than age 65, or have serious liver or kidney problems, your doctor may start you at the lowest dose (25 mg) of VIAGRA. If you are taking protease inhibitors, such as for the treatment of HIV, your doctor may recommend a 25 mg dose and may limit you to a maximum single dose of 25 mg of VIAGRA in a 48 hour period. If you are taking alpha-blocker therapy, you should not take a dose of greater than 25 mg of VIAGRA at the same time (within 4 hours) as your dose of alpha-blocker.

### • How To Take VIAGRA

Take VIAGRA about one hour before you plan to have sex. Beginning in about 30 minutes and for up to 4 hours, VIAGRA can help you get an erection if you are sexually excited. If you take VIAGRA after a high-fat meal (such as a cheeseburger and french fries), the medicine may take a little longer to start working. VIAGRA can help you get an erection when you are sexually excited. You will not get an erection just by taking the pill.

### • Possible Side Effects

Like all medicines, VIAGRA can cause some side effects. These effects are usually mild to moderate and usually don't last longer than a few hours. Some of these side effects are more likely to occur with higher doses. The most common side effects of VIAGRA are headache, flushing of the face, and upset stomach. Less common side effects that may occur are temporary changes in color vision (such as trouble telling the difference between blue and green objects or having a blue color tinge to them), eyes being more sensitive to light, or blurred vision.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including VIAGRA) reported a sudden decrease or loss of vision in one or both eyes. It is not possible to determine whether these events are related directly to these medicines, to other factors such as high blood pressure or diabetes, or to a combination of these. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including VIAGRA, and call a doctor right away.

In rare instances, men have reported an erection that lasts many hours. You should call a doctor immediately if you ever have an erection that lasts more than 4 hours. If not treated right away, permanent damage to your penis could occur (see *How Sex Affects the Body*).

Heart attack, stroke, irregular heart beats, and death have been reported rarely in men taking VIAGRA. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to VIAGRA.

VIAGRA may cause other side effects besides those listed on this sheet. If you want more information or develop any side effects or symptoms you are concerned about, call your doctor.

### • Accidental Overdose

In case of accidental overdose, call your doctor right away.

### • Storing VIAGRA

Keep VIAGRA out of the reach of children. Keep VIAGRA in its original container. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

### • For More Information on VIAGRA

VIAGRA is a prescription medicine used to treat erectile dysfunction. Only your doctor can decide if it is right for you. This sheet is only a summary. If you have any questions or want more information about VIAGRA, talk with your doctor or pharmacist, visit [www.viagra.com](http://www.viagra.com), or call 1-888-4VIAGRA.



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