Erectile Dysfunction



PRIMARY TREATMENT OPTIONS



This brochure, the second in a three-part series, focuses on erectile dysfunction, or ED. You may still hear it called "impotence," but today doctors usually will refer to it as ED, a more precise term because it refers to only erection problems. In this brochure, you will learn about oral therapies that may be used to treat this condition.

There are several different sexual problems a man may face:

- low libido, having little or no sex drive or interest in sex;
- ejaculatory difficulties, which can include premature ejaculation (reaching orgasm too soon) or delayed ejaculation (taking an extremely long time to reach an orgasm); and
- erectile dysfunction (ED), the persistent inability to get or maintain an erection firm enough for satisfactory sexual intercourse.

These conditions can overlap—one man may have more than one condition at the same time. The good news is that solutions are available for all of these problems to help a man and his partner enjoy a satisfying sexual relationship throughout life.

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Until relatively recently, a man who had trouble getting or keeping an erection was likely to suffer in silence. He may have thought of the problem as a personal failure or an unavoidable part of the aging process. He may have been too embarrassed to bring up the subject with his doctor, or just have assumed that there was no good solution, so the condition went untreated.

Several developments have changed that situation. Today we have not only a greater understanding of male sexual health, but also a broader array of treatment options to help a man achieve and maintain satisfying erections. And media attention on some of the treatment options has made it easier for a man to take the first step in resolving ED: discussing it with his partner and doctor.

WHAT IS ED?

Men who have ED have a problem getting or keeping an erection that's firm enough for sexual intercourse. All men have difficulties with erections from time to time. In some men it is infrequent or mild. In others it is a consistent, more severe problem. It can cause low self-esteem, performance anxiety, depression, stress and may affect the quality of a marriage or intimate relationship.

If you know or suspect you have ED, you are not alone. Studies show that about one half of American men over age 50 (or 30 million men in that age group) have some degree of ED. In seeking help for ED, it is also important to remember that an erection problem affects both partners in a relationship.

TREATMENT OPTIONS FOR ED

You've probably heard about or seen the ads for the oral medications that are used to treat ED. For most men, those pills are considered the first line of therapy. They are effective and, unlike some of the older methods, easy and convenient to use.

The oral medications are not the only solutions, however. Depending on your situation, your doctor might provide you with a number of additional choices. Like the decision to treat ED, selecting the kind of treatment to use is a personal decision that depends on the preferences of you and your partner.

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REVERSIBLE CAUSES

Before or while beginning treatment, your doctor may be able to significantly improve ED by treating an underlying cause.

LIFESTYLE OR PSYCHOLOGICAL FACTORS

Changing certain habits, such as stopping drug abuse, may improve or eliminate ED. Psychological problems, such as relationship conflicts, depression or performance anxiety, can also be successfully treated in many cases.

PRESCRIPTION OR NONPRESCRIPTION DRUG USE

If ED is a side effect of a medication you are taking, your doctor may be able to help you work around the problem by adjusting the dose of your medication or switching you to a different drug. However, don't stop taking your medicine or change your dosage without consulting your doctor first.

HORMONE THERAPY

If a blood test shows that your testosterone level is too low, the doctor may prescribe testosterone replacement therapy, particularly if you're experiencing diminished libido in addition to ED. This therapy can be administered in various ways, including: through regular injections, a gel applied to the skin or a patch that is worn on the skin.

MEDICATION FOR ED

Sildenafil citrate (Viagra®), vardenafil HCI (Levitra®) and tadalafil (Cialis®) are oral medications that have been demonstrated safe and effective for treating ED in a broad range of patients. Sildenafil citrate was the first of these three drugs approved by the U.S. Food and Drug Administration (FDA). It became available in 1998. Media attention about the drug led to greater public awareness of ED. As a result, more men and their partners felt comfortable talking about ED and asking for help with it. The FDA approved vardenafil HCI and tadalafil in 2003.

All three pills belong to a class of drugs known as phosphodiesterase type 5 (PDE-5) inhibitors. Though they work in the same way to help men have erections, there are differences among them. The differences include what the standard dose is, how long their effect lasts, which side effects are associated with them, and how they interact with food or other medications.

PDE-5 inhibitors work by relaxing the muscle cells in the erection chambers, enhancing blood flow into the penis and thereby helping to produce a rigid erection. When a man is sexually excited, his brain sends messages through the nerves to the penis. These nerves release a substance that relaxes the smooth muscle in the penis and allows for increased blood flow. The PDE-5 inhibitors

temporarily prevent (or inhibit) the breakdown of that natural substance.

In general, sildenafil citrate, vardenafil HCI and tadalafil are effective in about seven out of every 10 men with ED. They only work if a man is sexually stimulated, but they can be effective regardless of age, race or ED severity. Even men with severe or complete ED may respond to an oral PDE-5 inhibitor. They have been shown to help men who have ED that is of unknown cause or related to diabetes mellitus, high blood pressure, spinal cord injuries, a past heart attack (more than six months ago), heart bypass surgery and depression. These drugs are also helpful when ED is associated with antidepressant use or medicine used to treat high blood pressure. PDE-5 inhibitors should be tried in men who have ED following pelvic surgery; their effectiveness is generally less than in cases where men have only medical problems causing ED.

PRACTICAL TIPS

Studies show that many men who do not seem to respond to an oral PDE-5 inhibitor may not be taking the medication properly. These tips will help increase the likelihood that the treatment is effective. Additional information on how to take your oral PDE-5 inhibitor is found in the table on page 12.

TIMING IS IMPORTANT

All the PDE-5 inhibitors take some time to work and their effects last for only a set amount of time. It is recommended that these drugs be taken 30-60 minutes before sexual activity.

Sildenafil citrate works best on an empty stomach. Eating a heavy, fatty meal or drinking a lot of alcohol before taking sildenafil citrate can delay or prevent its effects. Tadalafil and vardenafil HCI can generally be taken without regard to meals, although a heavy, fatty meal may also slow the absorption of vardenafil HCI and delay its effects.

The effects of sildenafil citrate and vardenafil HCI may last for 30 minutes to four hours or longer. Tadalafil may be effective for up to 36 hours. This does not mean that you will have an erection that lasts for that length of time, but that tadalafil has a longer duration of activity in your system, giving you the opportunity for an erection. With all of the PDE-5 inhibitors, sexual stimulation is required to achieve an erection. If you take your medication and just sit in front of the television with no sexual stimulation, the medication will not work. These drugs are not designed to treat a lack of sexual desire, which is different from experiencing desire but not being able to get or maintain an erection.

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CONSIDER THE BIGGER PICTURE

Although oral PDE-5 inhibitor therapy is very effective in helping men achieve an erection, it will not magically restore an intimate relationship if there are other problems, too. This is especially true if a man has had long-term ED. Good communication between partners is required. Some couples benefit from sexual counseling and education that can help them identify and deal with psychological or relationship issues that affect their sex life.

Even men who respond to treatment with a PDE-5 inhibitor should pay attention to lifestyle factors that can affect ED. Make good food choices, get regular physical activity, and try to maintain normal weight and cholesterol levels. Drink alcohol only in moderation and don't smoke. Following this advice can help improve how you respond to drug treatment for ED and help prevent your ED from becoming worse. In other words, you can help the drug help you. At the same time, these steps will definitely have a positive effect on your overall health, quality of life and longevity.

WORK WITH YOUR DOCTOR TO FIND THE BEST DOSE FOR YOU

Sildenafil citrate, vardenafil HCI and tadalafil all come in various strengths. Your doctor will determine the best starting dose for you and may adjust the dose if the drug does not seem effective or is causing bothersome side effects. A lower starting dose is generally recommended for men over age 65, men on alpha blockers (for BPH or high blood pressure), those with severe liver or kidney disease, and in men who are taking certain medications, such as cimetidine (Tagamet™), erythromycin, ketoconazole or protease inhibitors. Do not change your dose without talking to your doctor.

Never take any of the PDE-5 inhibitors more than once a day. If you are taking certain medications or have kidney or liver problems, your doctor may limit you to taking one dose every two or three days.

All of these PDE-5 inhibitors are believed to be equally effective. Still, if your doctor has prescribed one of these drugs for you, and you are not happy with the results after a fair trial, ask your doctor about trying one of the other products.

Before giving up on one drug and switching to another, may sure you are using the drug correctly, and talk to your doctor about adjusting the

dose. Remember that the drugs are not magic. Even if your ED is due to physical problems, a history of ED may leave you nervous about your performance. You may need to try out ED treatment a few times to feel comfortable and relaxed, so you may not respond fully the first couple of times you take a PDE-5 inhibitor.

DON'T SHARE YOUR MEDICATION (OR OTHER ED TREATMENTS) WITH ANYONE

The PDE-5 inhibitors are for treatment of ED in men only. They should not be taken by women or children. None of the PDE-5 inhibitors are intended for use in men who do not have ED.

They do not:

- increase sexual desire
- increase sexual prowess in men with normal erectile function
- affect fertility
- · act as a male form of birth control
- protect against HIV or other sexually transmitted diseases

SIDE EFFECTS

As with any drug, there are some side effects associated with PDE-5 inhibitors. Most common are headaches, flushing (redness) of the face, running or stuffy nose, upset stomach, dizziness and muscle aches. Those side effects are usually mild, but taking the drug with alcohol may

make them worse. A few men who take a PDE-5 inhibitor, especially sildenafil citrate, may notice temporary changes in their color vision. Things may seem to have a blue tint or look brighter than usual. In 2005, reports emerged possibly linking decreased vision or sudden blindness with the use of PDE-5 inhibitors. This extremely rare type of vision loss is caused by low blood flow to the optic nerve and is known as non-arteritic anterior ischemic optic neuropathy (NAION). However, the condition has also been found in patients over age 50 who may also suffer from heart disease, diabetes, high blood pressure, high cholesterol, history of smoking or eye problems and is not connected exclusively to PDE-5 therapy. If you lose your eyesight while taking a PDE-5 inhibitor, get medical help immediately. More information from the FDA's Center for Drug Evaluation and Research can be found on line at www.fda.gov/cder.

Usually, side effects associated with PDE-5 inhibitors disappear in a few hours. They have been reported to last somewhat longer with tadalafil compared with sildenafil citrate or vardenafil. In particular, muscle aches and back pain associated with tadalafil may last up to 48 hours. Contact your doctor if you experience any side effects that are bothersome or do not go away.

Sildenafil, at the 50 mg and 100 mg doses, and all dosages of vardenafil should be administered

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with caution in patients taking alpha-blocker medications (see respective product information sheets for details).

SAFFTY CONSIDERATIONS

The PDE-5 inhibitors have helped many men with ED, and the FDA continues to indicate that they are safe and well-tolerated when taken as directed by men who have gotten approval from their doctors.

If you want to try one of these medications, talk to your doctor. Remember, ED is a medical condition that requires a doctor's evaluation before any treatment is prescribed. Never use a PDE-5 inhibitor without a prescription. Never get a prescription for sildenafil citrate, vardenafil HCI or tadalafil over the Internet or other nonstandard source. You run several risks:

- You may be buying a counterfeit product that does not have the same purity, strength or quality as the real drug.
- Your ED may be related to serious health problems that will be undetected and untreated if you don't get a medical examination.
- The medication may interact with other drugs you're taking, or may otherwise not be safe for you to take.

Never take any PDE-5 inhibitor if you are taking any medication that contains a nitrate. If you are not sure if you are taking a nitrate, ask your doctor. One of the most commonly used nitrates is nitroglycerin, which is often prescribed for angina (heart-related chest pain). Nitrates can be taken in several forms. There are pills that are swallowed and pills that are placed under the tongue. The drug is also available as a skin patch and in an inhaler.

When a PDE-5 inhibitor is used in combination with any nitrate, blood pressure may drop to dangerously low levels. For the same reason, PDE-5 inhibitors must not be used in combination with recreational drugs such as amyl nitrate, known as "poppers." Make sure you tell doctors, pharmacists and other health care providers if you take sildenafil citrate, vardenafil HCI or tadalafil even if only occasionally, so that you do not also receive a nitrate.

DRUG	AVAILABLE STRENGTHS	USUAL STARTING DOSE*
sildenafil citrate (Viagra®)	25, 50, 100 mg	50 mg
tadalafil (Cialis®)	5, 10, 20 mg	10 mg
vardenafil HCI (Levitra®)	2.5, 5, 10, 20 mg	10 mg

^{*} For men without liver or kidney disease and not taking medication of sildenafil and vardenafil is also lower in men over 65 years of

Tell your doctor if you are taking medicines called alpha-blockers. Alpha-blockers are medications that may be prescribed for a variety of reasons, including for the treatment of high blood pressure or prostate problems. Medications within this class include terazosin HCl (Hytrin®), tamsulosin HCl (Flomax®), doxazosin mesylate (Cardura®), prazosin HCl (Minipress®) and alfuzosin HCl (Uroxatral®).

Taking an alpha-blocker together with a PDE-5 inhibitor may lead to an unsafe, sudden drop in blood pressure. Your doctor will advise you about using a PDE-5 inhibitor and an alpha-blocker.

The PDE-5 inhibitors should be used cautiously in men with certain medical conditions:

- active stomach ulcers
- certain heart problems (e.g., heart failure)
- retinitis pigmentosa (a rare eye disease)

MAXIMUM DURATION	SHOULD I AVOID TAKING THIS MEDICATION WITH MEALS?
4 hours	Yes
36 hours	No
4 hours	No

ons that can affect PDE-5 inhibitor blood levels; the usual starting dose fage.

- a recent (within the past six months) stroke, heart attack or life-threatening arrhythmia
- abnormally low or elevated blood pressure
- liver or kidney problems
- · bleeding disorders
- a deformed penis shape or Peyronie's disease
- a history of a erection lasting more than four hours
- certain blood cell problems

Make sure your doctor knows if you have any of these conditions. If you have taken a PDE-5 inhibitor and then require emergency medical treatment, make sure you share that information with medical personnel.

SEX FOR HEART PATIENTS

If you know you have a heart condition and want to start treatment for ED, first ask your doctor if your heart can handle the extra strain of having sex. Because sex makes the heart work harder, sexual activity is not advisable for some men with certain heart problems. However, most men with the following cardiovascular conditions are safely able to be sexually active and use any of the current therapies for ED:

- controlled high blood pressure
- a past heart attack
- after a successful heart bypass operation

If you have never been diagnosed with a cardiovascular disease (a disease of the heart or blood vessels) your doctor will check out your health before prescribing ED treatment, with special attention to your risk factors for heart or circulatory disease. That's because ED may be a clue to undiagnosed cardiovascular disease or other disorders.

WHEN TO SEE A SPECIALIST

Newer, easy-to-administer medications for ED mean that primary care doctors, such as internists or family practice physicians, now routinely treat the condition. In some cases, your primary care doctor may refer you to a **urologist** who specializes in the treatment of ED, or a specialist to treat a disease or condition that may be an underlying cause of ED.

You may be sent to see a urologist if you don't respond to drug therapy, if your ED is complicated or if your primary care doctor decides you need a second opinion. Urologists, in addition to performing specialized evaluations, prescribe medications and perform surgery to correct erection problems.

GLOSSARY

benign prostatic hyperplasia (BPH): an enlarged prostate not caused by cancer; BPH can cause problems with urination because the prostate squeezes the urethra at the opening of the bladder.

diabetes mellitus: a condition characterized by high blood sugar resulting from the body's inability to use sugar (glucose) as it should; in Type 1 diabetes, the pancreas is not able to make enough insulin; in Type 2 diabetes, the body is resistant to using available insulin.

erectile dysfunction (ED): the inability to get or maintain an erection for satisfactory sexual intercourse.

ejaculation: release of semen from the penis during sexual climax.

erection: enlargement and hardening of the penis caused by increased blood flow into the penis and decreased blood flow out of it as a result of sexual excitement.

ferfility: the ability to conceive and have children.

high blood pressure: medical term is hypertension.

impotence: the precise term erectile dysfunction (ED) has largely replaced the word "impotence" because it refers only to erection problems.

libido: sexual desire.

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orgasm: the climax of sexual excitement, consisting of intense muscle tightening around the genital area experienced as a pleasurable wave of sensations through parts of the body.

phosphodiesterase type 5 (PDE-5) inhibitors: oral medications that are the first line of therapy for uncomplicated ED.

penis: the male organ used for urination and sex.

premature ejaculation: the inability to maintain an erection long enough for mutual satisfaction.

prostate: in men, a walnut-shaped gland that surrounds the urethra at the neck of the bladder; the prostate supplies fluid that goes into semen.

testosterone: male hormone responsible for sexual desire and for regulating a number of body functions.

Urethro: in males, this narrow tube carries urine from the bladder to the outside of the body and also serves as the channel through which semen is ejaculated; extends from the bladder to the tip of the penis.

urologist: a doctor who specializes in diseases of the male and female urinary systems and the male reproductive system. The American Urological Association
Foundation, Inc. (formerly the American Foundation for Urologic Disease, Inc.) is a charitable organization established to raise funds for research, lay education and patient advocacy for the prevention, detection, management and cure of urologic diseases.

The American Urological Association Foundation provides this information based on current medical and scientific knowledge. This information is not a tool for self-diagnosis or a substitute for professional medical advice. It is not to be used or relied on for that purpose. Please see your urologist or other health care provider regarding any health concerns and always consult a health care professional before you start or stop any treatments, including medications.

To obtain multiple copies of this brochure or others in our patient information library, please call 410-689-3990.

Single copies of these booklets are available free of charge by calling or writing:

American Urological Association Foundation, Inc. 1000 Corporate Blvd., Suite 410 Linthicum, MD 21090

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