

BEST BUY DRUGS



Evaluating Drugs Used to Treat:
Enlarged Prostate
Comparing Effectiveness, Safety, and Price



Our Recommendations

A man's prostate becomes larger as he ages, a condition known as benign prostatic hypertrophy, or BPH. It's usually not a serious or life-threatening condition, but it can cause problems with urinating, primarily in men age 50 and older.

Many men with BPH will either have no symptoms or symptoms that are mild and not that bothersome. But for millions of others, the urinary problems caused by BPH can be burdensome and interfere with their quality of life. Some men with BPH, for example, feel the urge to get up several times throughout the night to urinate, which can interrupt their sleep and leave them tired and groggy the next day. Concerns about urinary problems can also lead some men with this condition to give up routine activities such as sports or going to the movies where it may be difficult to find or reach a restroom.

You should see a doctor if you have urinary problems. The symptoms of BPH can be similar to the symptoms of prostate cancer, so it's important to get an accurate diagnosis. You should also contact your doctor immediately if you have a fever or chills, pain in your back, side or abdomen, cloudy or bloody urine, or pain when urinating. Those could be signs of serious complications that require medical attention.

If you have urinary problems due to BPH, lifestyle changes can often provide relief and should be tried first. Those include going to the bathroom when you first feel the urge, reducing or eliminating your intake of alcohol, caffeine, antihistamines, and decongestants, and limiting your fluid intake before bedtime.

If your symptoms persist or worsen, the next step is usually to consider medication. Two classes of drugs are commonly used to treat prostate enlargement: alpha-blockers and 5-alpha-reductase inhibitors. Alpha-blockers are generally used first because they act fast, relieving urination problems in a matter of days or weeks, while reductase inhibitors can take several months to provide relief. Sometimes the two types of drugs are used in combination.

If you and your doctor decide that a drug is appropriate for your condition, we recommend the alpha-blocker doxazosin as your first option. We picked it as our *Best Buy* because it has a long track record of being both safe and effective. It's also available as an inexpensive generic drug, costing \$10 or less for a month's supply. The savings would be significant compared to taking one of the costly brand-name alpha-blockers, which can run more than \$100 per month.

If doxazosin doesn't work for you, you might try another alpha-blocker, terazosin, also available as a low-cost generic. Or you and your doctor might want to consider adding a reductase inhibitor to your regimen. In that case, we recommend adding finasteride. It is the only reductase inhibitor available as a generic, so it costs significantly less than a brand-name drug. In addition, the combination of finasteride and doxazosin has been proven to delay the progression of BPH symptoms.

This report was released in April 2009.

Welcome

This report compares the effectiveness, safety, and cost of medicines used to treat urination problems due to prostate enlargement, a condition also known as benign prostatic hyperplasia (or hypertrophy), or BPH. It is based on an analysis of the scientific evidence on drugs to treat BPH, including studies from the 1960s through late 2008.

This report is part of a project by Consumers Union and Consumer Reports to help you find safe, effective medicines that give you the most value for your health-care dollar. To learn more about the project and other drugs we've evaluated for other diseases and conditions, go to www.ConsumerReportsHealth.org/BestBuyDrugs.

Prostate enlargement, or BPH, affects millions of men in the U. S., mostly those ages 50 and older. While it can be a serious condition in some cases, it's important to note that it is not prostate cancer and that many men who have been diagnosed with BPH have no symptoms at all or symptoms that are minor and not very bothersome.

It's also important to emphasize that BPH does not raise your risk of prostate cancer. The prostate becomes larger in *all* men as they age, and how slowly or rapidly that occurs does not appear to be linked to one's risk of prostate cancer. That said, BPH symptoms (see the list of symptoms on page 4) can be similar to the symptoms of prostate cancer. So it's important to be checked by a physician if you notice changes in your typical urination patterns or have other BPH symptoms. It's also possible to have BPH and prostate cancer at the same time, underscoring the need to get checked.

Almost all men—if they reach a certain age—will develop BPH. The statistics are not precise, but by age 55 or so, about half of all men have an enlarged prostate. By age 65, the figure is up to nearly 75 percent, and by age 80, nine in 10 men have BPH. But only about half of men will have symptoms that warrant treatment.

BPH symptoms, which usually involve problems with urinating, aren't hard to detect. And why they occur is pretty well understood. The normal function of the prostate is to produce semen, the fluid that carries sperm during ejaculation. The prostate surrounds the urethra, the tube that carries urine from the bladder and out of the body. When the prostate becomes enlarged, it pinches the urethra. This partly—and sometimes completely—restricts the flow of urine or causes difficulty urinating.

An enlarged prostate also triggers changes in your bladder. As the urethra becomes narrow, the bladder has to work harder, which can cause its walls to become thick. This can make your bladder contract when it contains only a small amount of urine. Your bladder can also become distended and lose its muscular tone. This combination of factors results in incomplete

bladder emptying, which can make you feel as though you have to urinate more often and lead to other problems.

The symptoms of BPH include:

- slowed or delayed start to urinating
- needing to urinate more often
- needing to urinate two or more times during the night
- weak flow of urine
- dribbling of urine after finishing
- straining to urinate
- strong and sudden urge to urinate
- feeling that the bladder is not completely emptied after urinating
- sudden inability to urinate
- incontinence (urine leakage)

Those symptoms can have a negative impact on your quality of life depending on their severity. Men who get up three or four times at night to urinate, for example, can be tired the following day. BPH can also inhibit some men from engaging in routine activities like sports or going to the movies because of anxiety about the need to use the restroom.

BPH symptoms are usually mild for most men. But when they become bothersome or even severe it's important to seek help because if left untreated, prostate enlargement can lead to such complications as urinary-tract infections and kidney damage. Also, contact your doctor immediately if you have fever or chills, pain in your back, side or abdomen, cloudy or bloody urine, or pain when urinating. Those symptoms could be a sign of complications that require medical attention.

What causes the prostate to enlarge as men become older and why it occurs in some men more than others is not well understood. A hormone related to testosterone, called dihydroxytestosterone, or DHT, is thought to play an important role. Some men prone to developing a more severely enlarged prostate may have higher than average DHT levels in their blood, or their prostates may become more sensitized to its effects after age 60.

Family history also plays a role. Men whose fathers and/or grandfathers had BPH are more likely to develop it. Some studies have suggested that black and Hispanic men may be more prone to urination problems related to BPH than white men, but recent studies have found little, if any, difference in rates of the condition by race.

There are several treatment strategies that can help provide relief. Lifestyle changes (these are discussed in the Treatment Options section on page 7) can often be enough, but if they fail to improve symptoms, then medication might be necessary.

Table 1. Classes of Drugs Used to Treat BPH

Generic Name	Brand Name	Available as a Generic Drug?
Alpha-blockers		
Alfuzosin extended release	Uroxatral	No
Doxazosin	Cardura	Yes
Doxazosin sustained release	Cardura XL	No
Prazosin ¹	Minipress	Yes
Silodosin	Rapaflo	No
Tamsulosin	Flomax	No ²
Terazosin	Hytrin	Yes
5-alpha-reductase inhibitors		
Dutasteride	Avodart	No
Finasteride	Proscar	Yes

¹ Prazosin is prescribed off-label to treat BPH.

² Patent is expiring in October 2009. Will probably become available as a generic in late 2009 or early 2010.

This report focuses on the two classes of drugs commonly used to treat prostate enlargement: alpha-blockers and 5-alpha-reductase inhibitors. Table 1, above, lists the seven alpha-blockers and two alpha-reductase inhibitors used to treat BPH. (The differences between the two drug classes are discussed later.)

This report was released in April 2009.



Who Needs a Drug for BPH?

As we have already mentioned, many men with BPH don't have symptoms or their symptoms can be managed with lifestyle changes. About half of men of any age who have BPH will have symptoms that require attention and treatment that may involve taking one of the drugs we evaluate in this report. The percentage of men requiring treatment increases with age:

- One in four men in their late 50s can expect to have symptoms that are bothersome enough to seek medical attention or treatment;
- One in three men in their late 60s can expect to have symptoms that are bothersome enough for them to seek medical attention or treatment, and
- One in two men in their late 70s and beyond can expect to have symptoms bothersome enough to seek medical attention or treatment.

This means that millions of men are regularly taking drugs or using other treatment options to ease the symptoms of BPH.

The first advice we'd give to any man bothered by problems when urinating is to see a doctor. Many men are reluctant to talk about urination problems with their doctor, but it's important to get these issues evaluated as early as possible to prevent any complications that may be present, whether or not the patient is aware of them. It's important to note that some men don't notice any symptoms of BPH and their enlarged prostate is only discovered by their physician during a routine examination.

Getting a diagnosis

Doctors should regularly ask all men over age 50 about urination problems. But if you are experiencing problems, you should bring them to your physician's attention even if he doesn't specifically ask you about them.

It's important to note that the size of your prostate does not always correlate with the severity of BPH symptoms. That is, some men with only slightly enlarged prostates can have quite bothersome symptoms, while others with substantially enlarged prostates may have few or no symptoms.

To gauge the severity of your symptoms, your doctor will likely ask you several questions about your urination problems (See Table 2, below). Those questions will include how often you feel the urge to go, how many times per night you wake up to use the restroom, and how much your urination problems affect the quality of your life. Your doctor will use your answers to these questions to determine how severe your problems are and the most appropriate treatment.

In addition, your doctor will also take your medical history, including whether you have any other conditions that may worsen your symptoms or that might affect your treatment options.

Your doctor might also perform a digital rectal exam (the insertion of a finger in the rectum to feel the prostate) to assess the firmness and size of your

Table 2. Questions your doctor will likely ask about your symptoms*:

Over the past month:

- How often have you had a sensation of not emptying your bladder completely after you finish urinating?
- How frequently have you urinated again less than two hours after you finished urinating?
- How difficult have you found it to postpone urination?
- How often have you had a weak urinary stream?
- How frequently have you had to push or strain to begin urination?
- How many times did you typically get up to urinate from the time you went to bed until the time you got up for good?

And finally:

- If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?

*List is adapted from the International Prostate Symptom Score questionnaire.

prostate. The American Cancer Society recommends that all men undergo a digital rectal exam starting at age 50 to screen for prostate cancer, but you should know that there is considerable disagreement about whether this procedure is useful and whether it should be performed at all. In fact, some medical organizations, including the American College of Preventive Medicine, do not recommend the digital rectal exam as a screening tool for prostate cancer. The procedure alone might not detect infection, kidney problems, or prostate cancer, or discern between a prostate that is enlarged due to BPH or cancer.

Most likely your doctor will also do some simple tests to check for infection and make sure your kidneys are fine.

Your doctor should then discuss the blood test for prostate cancer, called the prostate-specific antigen, or PSA, test. There are pros and cons of administering this test, especially if you have any signs of infection. In that case your infection should be treated and further testing delayed.

It is important to understand the pros and cons before you have a PSA test. The test is not as accurate as we would like it to be. Although it was initially thought that elevated PSA levels indicated prostate cancer, in fact, many men with the cancer have low PSA levels, while those who do not have prostate cancer can have elevated PSA levels. Recent large-scale studies have shown that while PSA tests might detect prostate cancer early, this has little, if any, reduction on a man's chances of dying from the disease. This is worrisome, because a positive PSA test can lead to more aggressive prostate-cancer treatments, which can have significant side effects, such as difficulty getting erections and trouble controlling urination. And as men grow older, especially over 75, detecting prostate cancer early is less important, since the cancer grows more slowly at older ages and often does not affect life span. The American Urological Association now recommends PSA testing for all men starting at age 40 who are in good health. But this is a controversial guidance that contradicts the recommendations of other organizations. Given these uncertainties, we advise the current recommendations from the U.S. Preventive Services Task Force, which are that doctors should discuss the benefits and risks of the PSA test and prostate-cancer treatment with men under the age of 75 before ordering the test. The task force also recommends

against prostate-cancer screening for men over 75 because there is little, if any, benefit.

In some cases of urination problems, your doctor may want to do additional tests to establish the diagnosis. One is called a post-void residual volume test, which measures how much urine is left in the bladder after urinating. Ultrasound techniques can also be used to check the size and structure of the prostate.

Treatment options

If your doctor diagnoses BPH and you have only mild symptoms or they are not too bothersome, he or she is likely to suggest “watchful waiting” and some lifestyle adjustments. The term “watchful waiting” means that you won’t be offered any specific treatments, but that you and your doctor commit to closely monitoring your symptoms over time to see if they worsen. That may include keeping a diary of symptoms and urination patterns or problems.

Lifestyle adjustments aren’t a treatment per se but they have been shown to be highly effective at both reducing symptoms and improving one’s quality of life. Table 3 on page 8 lists commonly used measures. They include going to the bathroom when you first feel the urge rather than waiting, and reducing or eliminating your intake of alcohol and caffeine. It’s also a good idea not to drink a lot of fluids in a short time-span or two hours before bedtime.

Getting regular exercise is promoted as helpful for reducing BPH, but there’s no good evidence that this works consistently. Kegel exercises—contracting the muscles that regulate urine flow—are known to help build control over urination. While good evidence showing this improves urination problems due to BPH is lacking, it can be worth trying. If possible, you should avoid over-the-counter cold and sinus medications containing decongestants or antihistamines, since those drugs can worsen the symptoms of prostate enlargement.

If you’re taking diuretic drugs, you should ask your doctor whether the dose can be reduced or if you can take a different medication, since either could improve your symptoms. Men with diabetes should work with their doctor to make sure their blood sugar levels are kept in control because if they aren’t, it can lead to increased urination.

If your symptoms don't improve with lifestyle changes or if they worsen, medication is typically the next step.

Other treatments

Various herbal supplements are touted as a treatment for urination problems due to BPH. These include saw palmetto, beta-sitosterol, rye-grass pollen, and Pygeum africanum. Some studies have suggested that those herbs may be effective, but many of the studies were small and not well done. That makes the results unreliable. Also, most of the studies followed men for less than six months, so it's not clear if the benefits of these products last longer than that.

We would urge caution in using any herbal supplements and advise you to discuss them with your doctor to make sure they are not interacting with any other medicines you take.

Surgery and other procedures

Surgery is typically reserved for men with complications, including recurrent blood in the urine, recurrent urinary-tract infections, kidney failure, and bladder stones. Surgery will likely be necessary if your BPH becomes so bad that you cannot urinate at all. Surgery can also be an option for men who can't take medications for other health reasons or in cases where prescription medications haven't worked well.

A number of surgical procedures are used to reduce prostate enlargement and the associated symptoms. These techniques remove tissue from the prostate that may be blocking urine flow. Your doctor will review the risks and benefits of the different procedures if you need surgery.

There are also nonsurgical procedures, such as microwave therapy, that shrink or kill obstructing prostate tissue. Again, your doctor can give you more information about those options if they are right for your situation.

Table 3. Lifestyle Changes That May Relieve Mild Symptoms of Prostate Enlargement

These measures can be helpful:

- Urinate when you first feel the urge; don't wait.
- Do not rush urination. Take your time and relax before, during, and after to give your bladder extra time to empty if the stream is slow or intermittent.
- Practice "double-voiding": Urinate as much as possible, relax for a moment, and then go again.
- Urinate before car trips, meetings, or movies.
- Spread fluid intake throughout the day and reduce it before bedtime, especially coffee, tea, or caffeinated beverages. Do not avoid fluid intake to reduce the need to urinate. That can cause dehydration.
- Drink alcohol and caffeine in moderation.
- Avoid antihistamines and decongestants when possible.
- If you take a diuretic (a type of high blood pressure pill), ask your doctor if you can take a lower dose or a different drug.
- If you have diabetes, controlling blood sugar can reduce frequent urination.

There's no clear evidence these work:

- Exercise
- Kegel exercises
- Herbal supplements such as saw palmetto, Pygeum africanum, rye-pollen grass, and beta-sitosterol.

Choosing a BPH Drug—Our *Best Buy* Picks

As mentioned earlier, there are two main groups of drugs commonly used to treat BPH: alpha-blockers and 5-alpha-reductase inhibitors. (See Table 4, below, and Table 5 on page 10 for the commonly used dosages and for a brief description of how they differ.)

Your doctor is most likely to prescribe an alpha-blocker as the first line of treatment if you need a drug to treat your BPH. That's primarily because those drugs take effect quickly and—for most men—help relieve urination problems and other symptoms in a matter of days or weeks. About 60 percent of men treated with alpha-blockers experience an improvement in their symptoms.

Alpha-blockers are also less expensive than the 5-alpha-reductase inhibitors. The three oldest alpha-blockers—immediate-release doxazosin (Cardura), prazosin (Minipress), and terazosin (Hytrin)—are available in lower-cost generic forms, and typically cost less than \$35 for a month's supply. (See Table 6 on page 13.) Prazosin is generally not used to treat urinary problems due to prostate enlargement

because it is not approved by the Food and Drug Administration (FDA) for the condition. It is also less convenient because it must be taken twice per day, whereas the other alpha-blockers are taken once daily. But prazosin, which is FDA-approved to treat high blood pressure, is sometimes an option if you have both urinary problems from an enlarged prostate and high blood pressure.

Three newer alpha-blockers—alfuzosin (Uroxatrol), tamsulosin (Flomax), and doxazosin-sustained release (Cardura XL)—are available in extended-release or continuous-release forms designed to keep them working in your body all day long. That may have advantages for some patients, but our analysis found no compelling evidence to indicate that those three medicines were any better than the older, immediate-release alpha-blockers in terms of reducing symptoms or improving quality of life.

Moreover, those longer-acting drugs are significantly more expensive than the immediate-release formulations. Flomax, which is one of the most expen-

Table 4. Common Dosages of BPH Drugs

Generic Name (Brand Name)	Starting Dosage	Maintenance Dosage
Alfuzosin extended release (Uroxatrol)	10 mg daily	10 mg daily
Doxazosin (Cardura)	1 mg daily	2 mg to 8 mg daily
Doxazosin extended release (Cardura XL)	4 mg daily	4 mg or 8 mg daily
Prazosin (Minipress)	1 mg daily	2 mg to 10 mg daily
Silodosin (Rapaflo)	4 mg to 8 mg daily	4 mg to 8 mg daily
Tamsulosin (Flomax)	0.4 mg daily	0.4 mg or 0.8 mg daily
Terazosin (Hytrin)	1 mg daily	2 mg to 10 mg daily
Finasteride (Proscar)	5 mg daily	5 mg daily
Dutasteride (Avodart)	0.5 mg daily	0.5 mg daily

Table 5. Description of BPH Drugs and their Side Effects

Type of medication	Main action	Common side effects
Alpha-blockers (alfuzosin, doxazosin, prazosin, silodosin, tamsulosin, terazosin)	Relaxes muscles in bladder	<ul style="list-style-type: none"> • Dizziness • Headache • Stomach problems • Reduced semen during ejaculation
5-alpha-reductase inhibitors (finasteride, dutasteride)	Shrinks prostate tissue by blocking a hormone	<ul style="list-style-type: none"> • Decreased sex drive • Decreased ability to get and keep an erection • Ejaculation problems

sive alpha-blockers, has a unique issue when it comes to cost. It is only available in one dosage strength, so if you need to increase your dose to get relief from your symptoms, you will need to take two pills, which doubles the cost. The other alpha-blockers are available in varying strengths for about the same price, so even if you need a stronger dose, it will cost you about the same.

Another point to keep in mind when it comes to cost is that you can save money by buying higher-dose tablets and splitting them in half with your doctor's or pharmacist's approval. (You can only split pills that are immediate release tablets, such as doxazosin and terazosin. Splitting should not be done with extended-release or sustained-release tablets). For example, if you are taking 4 mg of doxazosin per day, you could buy the 8 mg pill for about the same price and split it. You should use a pill-splitter to make certain that the two halves are the same size and provide you with the correct dose. These devices cost about \$5 to \$10 and are widely available.

Studies indicate that all alpha-blockers yield about the same clinical results in controlling symptoms and improving quality of life. Unfortunately, only a few studies directly compare the different alpha-blockers head to head. But to date they have found no advantage for one alpha-blocker over another.

Also, little research has been done on whether race or age makes a difference in how men respond to the BPH drugs. Some major studies have included very elderly men and black men, but so far there is no definitive evidence that the effectiveness or side effects of treatment differ between black and white men or older men.

Silodosin (Rapaflo) is the newest alpha-blocker. The FDA approved this medicine in late 2008. In two studies involving a total of 923 men, those receiving Rapaflo showed an improvement in their symptoms and urinary-flow rate compared with those who took a placebo pill over 12 weeks. But since the drug does not have the long track record of use of some of the other alpha-blockers, its safety profile is not yet firmly established. In addition, it's more expensive. For those reasons, we'd advise it not be used as initial treatment at this time.

How the drugs work

The 5-alpha-reductase inhibitors work in a much different way than the alpha-blockers. While the alpha-blockers relax muscles in the bladder, the 5-alpha reductase inhibitors actually shrink the prostate by blocking the abnormal buildup of the hormone DHT—a testosterone derivative—that can cause it to swell and become enlarged. The 5-alpha-reductase inhibitors help relieve symptoms but can take as long as 6 to 12 months before they work. And studies show they are much more likely to be effective in men with more severely enlarged prostates.

The two 5-alpha-reductase inhibitors are finasteride (Proscar and generic) and dutasteride (Avodart). Finasteride is also sold under the name Propecia as a treatment for male pattern baldness, but this is a lower-dose tablet that is not approved by the FDA for treating BPH. Generic finasteride costs less than Avodart but it's still more expensive than the generic alpha-blockers.

Studies don't indicate any difference in the effectiveness or safety of finasteride and dutasteride, and at

the current time neither is known to have any advantages over the other.

The 5-alpha-reductase inhibitors are sometimes prescribed initially, before an alpha-blocker, but this is quite rare. They are more commonly prescribed if an alpha-blocker has failed to relieve your symptoms or as a second drug to augment an alpha-blocker if you are not getting enough relief. There's more about this combination therapy on page 12.

One potential benefit of the 5-alpha-reductase inhibitors is that they might reduce the risk of developing prostate cancer. However, you should be aware that there is debate among experts about whether those drugs actually increase the risk of cancers that are more difficult to treat. As this report goes to print, the controversy has not been fully resolved to our satisfaction. This is an issue you need to discuss with your doctor to make the best-informed decision you can.

Side effects

You and your doctor's choice of a BPH drug may be based more on its side effect profile than effectiveness.

The most common side effects of alpha-blockers are reduced semen during ejaculation, headache, upset stomach, and stuffy or runny nose. The drugs can also cause low blood pressure, dizziness, and fainting, especially when you first start taking them, so it's important to take precautions to prevent any injuries that could result from this. That includes taking the drug before you go to sleep, so you're already laying down if problems do occur, and not driving or operating machinery when you first start taking it.

With the older drugs—doxazosin, terazosin, and prazosin—your doctor should start you on a low dose and build up to a higher dose over a period of a few weeks to give your body time to adjust to the medicine. That process is not necessary with the newer alpha-blockers (Flomax, Rapaflo, and Uroxatral).

Low blood pressure caused by the alpha-blocker medicines can fall to dangerous levels if you're also taking a high blood pressure drug or erectile dysfunction medicines such as sildenafil (Viagra), vardenafil (Levitra), and tadalafil (Cialis). So don't take an alpha-blocker with those other drugs without first discussing it with your doctor.

Men with prostate enlargement who are planning to have cataract surgery should be aware that all alpha-blockers can cause a complication called intraoperative floppy iris syndrome, or IFIS. This condition causes the iris of the eye to become limp due to increases in fluid levels in the eye. This is a concern because it can raise the risk of a painful and extended recovery period from cataract surgery and a reduction in visual acuity or sharpness after the surgery. You should alert your eye surgeon that you are taking alpha-blockers if you plan on having this surgery.

In very rare cases, the alpha-blockers can cause painful erections that last for hours. If not treated, this can lead to a permanent inability to achieve erection, so you should seek immediate medical attention if you develop this condition.

The side effects of the 5-alpha-reductase inhibitors may include a reduced sex drive and difficulty achieving and maintaining an erection. While these can be bothersome for many men, in clinical studies only around 2 percent of those who developed any sexual difficulties found them to be severe enough to stop taking the medicines.

The 5-alpha-reductase inhibitors can also cause birth defects in developing fetuses. So men should avoid using 5-alpha-reductase inhibitors when planning a pregnancy with their female partners, and the medicines should not be handled by women who are pregnant or planning to become pregnant.

Finally, the 5-alpha-reductase inhibitors can reduce levels of prostate specific antigen, or PSA, that is used to screen for prostate cancer. Patients who are appropriate candidates for these drugs tend to have higher PSA levels, but if the medicines lower their PSA levels it could make it more difficult to detect prostate cancer. There are strategies that attempt to account for this issue when reading the results of PSA tests, so make sure your doctor is aware that you are taking one of these drugs if your PSA level is being tested.

Our Best Buy Pick

For initial treatment of BPH, we have ruled out three of the alpha-blockers: silodosin (Rapaflo) because it is too new; prazosin because it is not FDA-approved for treating BPH and its twice-per-day dosing makes

it more inconvenient than the other alpha-blockers; and tamsulosin (Flomax) because of its higher cost while not being any more effective or safer than the other medicines. We would also advise against alfuzosin (Uroxatral) and Cardura XL, since they are more expensive and their extended-release formulation has not been proven to be safer or more effective than the older alpha-blockers.

That leaves two generic alpha-blocker drugs for consideration: doxazosin and terazosin. Given that there is no evidence that either of those is more effective or safer than the other, we have chosen generic doxazosin as our *Best Buy* for initial treatment of BPH due largely to its lower cost.

This medicine has been on the market for several decades, so its safety and effectiveness profile is well established. And a month's supply costs less than \$10. If doxazosin works for you, the savings would be significant over taking one of the costly brand-name alpha-blockers.

If doxazosin does not bring enough relief, you should try terazosin next. Or you could also try adding finasteride.

Combination therapy?

For men who do not get enough relief from an alpha-blocker, adding a 5-alpha-reductase inhibitor is an option. Again, your doctor is unlikely to recommend this unless your prostate is significantly enlarged and your symptoms are bothersome.

But be warned: This may not bring immediate relief. Studies indicate that combination treatment with an

alpha-blocker and a 5-alpha-reductase inhibitor doesn't generally provide additional benefit over an alpha-blocker alone in the first 12 months of treatment. Over the long-term, however, combination therapy appears to help prevent the symptoms from becoming worse. And it can also prevent serious complications, such as not being able to urinate at all (called acute urinary retention), which often leads to prostate surgery.

One study, for example, found that after four years of treatment with both the alpha-blocker doxazosin and the 5-alpha-reductase inhibitor finasteride, symptoms worsened in only 5.3% of the men compared with about 10% of those who received either drug alone. Men with the greatest prostate enlargement got the most benefit from the combination therapy. Another study involving the combination treatment of the alpha-blocker tamsulosin and the 5-alpha-reductase inhibitor dutasteride (Avodart) in men with very large prostates found that both drugs together provided greater improvement in symptoms after one and two years of treatment than either drug alone.

However, due to the increased risk of side effects with combination therapy, this treatment strategy is typically limited to men with bothersome symptoms and very enlarged prostates.

If you and your doctor decide that a combination strategy is appropriate for your condition, we recommend that you try doxazosin plus finasteride. This is the only combination treatment that has been proven to have a long-term benefit of delaying progression of symptoms over four years. In addition, as previously noted, both drugs are available as less-expensive generics.

Table 6. BPH Drugs – Cost Comparison

Generic Name and Dose	Brand name ¹	Number of pills per day ²	Average monthly cost ³
Alpha-blockers			
Alfuzosin 10 mg sustained-release tablet	Uroxatral	One	\$128
CR BEST BUY Doxazosin 1 mg tablet	Generic	One	\$10
Doxazosin 1 mg tablet	Cardura	One	\$58
CR BEST BUY Doxazosin 2 mg tablet	Generic	One	\$9
Doxazosin 2 mg tablet	Cardura	One	\$57
CR BEST BUY Doxazosin 4 mg tablet	Generic	One	\$9
Doxazosin 4 mg tablet	Cardura	One	\$63
CR BEST BUY Doxazosin 8 mg tablet	Generic	One	\$8
Doxazosin 8 mg tablet	Cardura	One	\$65
Doxazosin 4 mg sustained-release tablet	Cardura XL	One	\$64
Doxazosin 8 mg sustained-release tablet	Cardura XL	One	\$64
Prazosin 1 mg capsule	Generic	Two to Three	\$12-\$18
Prazosin 1 mg capsule	Minipress	Two to Three	\$56-\$84
Prazosin 2 mg capsule	Generic	Two to Three	\$14-\$21
Prazosin 2 mg capsule	Minipress	Two to Three	\$76-\$114
Prazosin 5 mg capsule	Generic	Two to Three	\$16-\$24
Prazosin 5 mg capsule	Minipress	Two to Three	\$126-\$189
Silodosin 8 mg capsule ⁴	Rapaflo	One	<i>Price not available</i>
Tamsulosin continuous delivery capsule 0.4 mg	Flomax	One to Two	\$123-\$246
Terazosin 1 mg capsule	Generic	One	\$33 ⁵
Terazosin 1 mg capsule	Hytrin	One	\$76
Terazosin 2 mg capsule	Generic	One	\$33 ⁵
Terazosin 2 mg capsule	Hytrin	One	\$79
Terazosin 5 mg capsule	Generic	One	\$33 ⁵
Terazosin 5 mg capsule	Hytrin	One	\$122
Terazosin 10 mg capsule	Generic	One	\$34 ⁵
Terazosin 10 mg capsule	Hytrin	One	\$72
Terazosin 10 mg tablet	Generic	One	\$51
5-alpha-reductase inhibitors			
Dutasteride 0.5 mg capsule	Avodart	One	\$127
Finasteride 5 mg tablet	Generic	One	\$75
Finasteride 5 mg tablet	Proscar	One	\$111

1. 'Generic' indicates that it's the generic version of the drug.

2. As typically prescribed.

3. Prices reflect nationwide retail average for February 2009, rounded to the nearest dollar if you were to pay the cash price. Information derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite®. Wolters Kluwer Health is not involved in our analysis or recommendations.

4. Silodosin (Rapaflo) had not yet gone on sale when this report was developed, so price data was not available. Watson, the maker of Rapaflo, told *Consumer Reports Best Buy Drugs* that the drug's price will be comparable to that of Flomax and Uroxatral.

5. Weighted averages were used to calculate the generic version of terazosin for 1 mg, 2 mg, 5 mg, and 10 mg capsules.

Talking With Your Doctor

It's important for you to know that the information we present here is not intended to substitute for a doctor's judgment. But we hope it will help you and your doctor arrive at a decision about which drug or drugs to treat BPH are best for you, and which gives you the most value for your health-care dollar.

Bear in mind that many people are reluctant to discuss the cost of medicines with their doctors, and that studies show doctors do not routinely take price into account when prescribing medicines. Unless you bring it up, your doctors may assume that cost is not a factor for you.

Many people (including physicians) also believe that newer drugs are always or almost always better. While that's a natural assumption to make, the fact is that it's not true. Studies consistently show that many older medicines are as good as, and in some cases better than, newer medicines. Think of them as "tried and true," particularly when it comes to their safety record. Newer drugs have not yet met the test of time, and unexpected problems can and do crop up once they hit the market.

Of course, some newer prescription drugs are indeed more effective and safer. Talk with your doctor about the pluses and minuses of newer vs. older medicines, including generic drugs.

Prescription medicines go "generic" when a company's patents on a drug lapse, usually after about 12 to 15 years. At that point, other companies can make and sell the drug.

Generics are almost always much less expensive than newer brand-name medicines, but they are not lesser-quality drugs. Indeed, most generics remain useful medicines even many years after first being marketed. That is why today about more than 50% of all prescriptions in the U.S. are for generics.

Another important issue to talk with your doctor about is keeping a record of the drugs you are taking. There are several reasons for this:

- First, if you see several doctors, each may not be aware of medicines the others have prescribed.
- Second, since people differ in their response to medications, it is very common for doctors to prescribe several medicines before finding one that works well or best.
- Third, many people take several prescription medications, nonprescription drugs and dietary supplements at the same time. These can interact in ways that can either reduce the benefit you get from the drug, or be dangerous.
- And fourth, the names of prescription drugs—both generic and brand—are often hard to pronounce and remember.

For all these reasons, it's important to keep a written list of all the drugs and supplements you are taking, and to periodically review this list with your doctors.

Always be sure, too, that you understand the dose of the medicine being prescribed for you and how many pills you are expected to take each day. Your doctor should tell you this information. When you fill a prescription at the pharmacy, or if you get it by mail, you should check to see that the dose and the number of pills per day on the pill bottle match the amounts that your doctor told you.

How We Picked the *Best Buy* Drugs for BPH

Our evaluation of medicines used to treat urinary problems due to BPH is based primarily on a systematic review conducted by researchers at the U.S. Department of Veterans Affairs and Oregon Health & Science University Evidence-based Practice Center. Researchers screened studies conducted from 1966 through July 2006 and focused on 62 that were well-conducted, and closely examined the effectiveness and/or safety of the drugs. A consultant to *Consumer Reports Best Buy Drugs* is also a member of the Oregon-based research team, which has no financial interest in any pharmaceutical company or product.

The full review of drugs for BPH is available at <http://www.hsrp.research.va.gov/publications/esp/BPH-2007.pdf> (This is a long and technical document written for physicians and researchers.)

In addition, we adapted material from *Consumer Reports Health*, an online subscription Web site presenting treatment options and Ratings (See ConsumerReportsHealth.org).

Consumers Union and *Consumer Reports* is solely responsible for selecting the *Best Buy Drugs*. Our methodology is described in more detail in the Methods section at ConsumerReportsHealth.org/BestBuyDrugs.

About Us

Consumers Union, publisher of *Consumer Reports*[™] magazine, is an independent and nonprofit organization whose mission since 1936 has been to provide consumers with unbiased information on goods and services and to create a fair marketplace. Consumers Union's main Web site is ConsumersUnion.org. The magazine's Web site is ConsumerReports.org.

Consumer Reports Best Buy Drugs[™] is a public education project administered by Consumers Union and can be found online at www.ConsumerReportsHealth.org/BestBuyDrugs. It is partially grant-funded. Principal current outside funding comes from the state Attorney General Consumer and Prescriber Education Grant Program, which is funded by the multistate settlement of consumer-fraud claims regarding the marketing of the prescription drug Neurontin.

The Engelberg Foundation provided a major grant to fund the creation of the project from 2004 to 2007. Additional initial funding came from the National Library of Medicine, part of the National Institutes of Health.

A more detailed explanation of the project is available at ConsumerReportsHealth.org/BestBuyDrugs.

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