# **ConsumerReports** Health **BEST BUY DRUGS**<sup>™</sup>

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



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# **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. These 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 \$8 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 updated in May 2012.

# 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.CRBestBuyDrugs.org.

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 5) 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—once 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

Table 1. Classes of Drugs Used to Treat BPH						
Generic Name	Brand Name	Available as a Generic Drug?				
Alpha-blockers						
Alfuzosin extended-release	Uroxatral	Yes				
Doxazosin	Cardura	Yes				
Doxazosin sustained-release	Cardura XL	No				
Prazosin <sup>1</sup>	Minipress	Yes				
Silodosin	Rapaflo	No				
Tamsulosin	Flomax	Yes				
Terazosin	Hytrin	Yes				
5-alpha-reductase inhibitors						
Dutasteride	Avodart	No				
Finasteride	Proscar	Yes				

1 Prazosin is prescribed off-label to treat BPH.

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)

These 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. These 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 dihyroxytestosterone, 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 (which are discussed in the Treatment Options section starting on page 8) can often be enough, but if they fail to improve symptoms, then medication might be necessary.

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

The erectile dysfunction medication, tadalafil (Cialis), is approved for treating enlarged prostate symptoms, and a combination pill, Jalyn, which contains both dutasteride and tamsulosin, is also available. Neither of those were included in the analysis that forms the basis of this report, so we do not discuss them. However, the pros and cons of combination therapy with an alpha blocker and a 5-alpha-reductase inhibitor are discussed on page 13.

This report was updated in May 2012.

# 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 urinate, 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 take your medical history into consideration, including whether you have any other conditions that may worsen your symptoms or that might affect your treatment options. Your doctor will likely also do some sim-

# Table 2. Questions your doctor will likely askabout 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.

ple blood and urine tests to check for infection and make sure your kidneys are functioning normally.

Your doctor might also perform a digital rectal exam (the insertion of a finger into the rectum) to assess the size and firmness of your prostate and to check for the presence of lumps that might be an indication of prostate cancer, and/or discuss doing a blood test for prostate cancer, called the prostate-specific antigen, or PSA test. But you should know that there is considerable disagreement not only about the usefulness of these procedures but also whether they should be performed at all. For example, the U.S. Preventive Services Task Force recently recommended against the PSA test for men of all ages because their view of the evidence is that the test is more likely to lead to substantial harms than to save lives. However, other groups, such as the American Urological Association and the American Cancer Society, do not recommend against the PSA test. A thorough discussion of the pros and cons of these procedures is beyond the scope of this report, but if you would like to learn more about them, you can read about PSA screening on our website: http://www.consumerreports.org/health/ conditions-and-treatments/prostate-cancer-screening/overview/index.htm.

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

# Table 3. Lifestyle Changes That May RelieveMild 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.

life. Table 3, above, 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-thecounter cold and sinus medications containing decongestants or antihistamines, since these 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 doing either could potentially 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.

# 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 Tables 4 and 5 on pages 11 and 12, respectively, for the commonly used dosages and for a brief description of how they differ.)

Your doctor is most likely to prescribe an alphablocker 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 5alpha-reductase inhibitors. The three oldest alphablockers—immediate-release doxazosin (Cardura), prazosin (Minipress), and terazosin (Hytrin)—are available in lower-cost generic forms that typically cost less than \$30 for a month's supply. (See Table 6 on page 14.) 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 alphablockers 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 sustainedrelease (Cardura XL)—are available in extendedrelease 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, both the brand-name and generic versions of those longer-acting drugs are significantly more expensive than the immediate-release formulations. Flomax, which is one of the most expensive alphablockers, has a unique issue regarding 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. The generic version of tamsulosin has the same problem. Just like its brand name counterpart, the generic tamsulosin is only available in one dosage strength, so if you need to increase your dose, you will still have to pay double.

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.

Be sure to check prices at online pharmacies and large discount stores, too. Those outlets often have significantly lower prices. Other options include the programs offered by large chains, such as CVS, Target, Walgreens and Wal-Mart, where a 30-day supply of certain generic drugs costs just \$4 or even less. We note in the price chart on page 14 which of the medications discussed in this report are likely available through those programs.

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 alphablockers 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

Table 4. Common Dosages of BPH Drugs					
Generic Name (Brand Name)	Starting Dosage	Maintenance Dosage			
Alfuzosin extended-release (Uroxatral)	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			

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. At \$159-\$163 per month, depending on dose, it is one of the most expensive alpha-blockers, and costs significantly more than generic doxazosin, which runs \$8 or less per month. 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 alphablockers 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 13.

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,

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> <li>Dizziness</li> <li>Headache</li> <li>Stomach problems</li> <li>Reduced semen during ejaculation</li> </ul>			
5-alpha-reductase inhibitors (finasteride, dutasteride)	Shrinks prostate tis- sue by blocking a hormone	<ul><li>Decreased sex drive</li><li>Decreased ability to get and keep an erection</li><li>Ejaculation problems</li></ul>			

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. However, the FDA in April 2012 updated the label of finasteride (Proscar and Propecia) to note that men have reported decreased libido and problems with ejaculation and orgasms that continued for weeks to months after they stopped taking the medications. Although those sexual side effects have not been clearly linked to Propecia or Proscar, the FDA said they were added to the labels because the reports indicate the drugs could cause a broader range of side effects that men should be aware of if they consider taking one of these medications.

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 two of the alpha-blockers: silodosin (Rapaflo) because it is very expensive and does not have the long track record of safety and effectiveness that other alphablockers do, and prazosin because it is not FDAapproved for treating BPH and its twice-per-day dosing makes it more inconvenient than the other alpha-blockers. We would also advise against alfuzosin (Uroxatral and generic) 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 three generic alpha-blocker drugs for consideration: doxazosin, tamsulosin, and terazosin. Given that there is no evidence that any of these is more effective or safer than the others, we have chosen generic doxazosin as our *Best Buy* for initial treatment of BPH due largely to its lower cost.

Doxazosin has been on the market for several decades, so its safety and effectiveness profile is well-established. And a month's supply costs \$8 or less, depending on dose. 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 could try terazosin next. Or you could also try adding finasteride. Generic tamsulosin may be an option to consider if you don't respond well to doxazosin or terazosin. However, as we previously noted, tamsulosin is only available in one dosage strength, so if you need to increase your dose, you will have to pay double.

#### **Combination therapy?**

For men who do not get enough relief from an alphablocker, 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-alphareductase 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 this strategy is appropriate, we recommend doxazosin plus finasteride. This is the only combination treatment proven to have a longterm benefit of delaying progression of symptoms over four years. And, as previously noted, both drugs are available as less-expensive generics.

#### Table 6. BPH Drugs – Cost Comparison

Note: If the price box contains a (s), that indicates the dose of that drug is likely available for a low monthly cost through programs offered by large chain stores. For example, Kroger, Sam's Club, Target, and Walmart offer a month's supply of selected generic drugs for \$4 or a three-month supply for \$10. Other chain stores, such as Costco, CVS, Kmart, and Walgreens, offer similar programs. Some programs have restrictions or membership fees, so check the details carefully for restrictions and to make sure your drug is covered.

	Generic Name and Dose	Brand name <sup>1</sup>	Number of pills per day <sup>2</sup>	Average monthly cost <sup>3</sup>
	Alpha-blockers			
	Alfuzosin 10 mg sustained-release tablet	Generic	One	\$82
	Alfuzosin 10 mg sustained-release tablet	Uroxatral	One	\$161
BEST BUY	Doxazosin 1 mg tablet	Generic	One	\$8 💲
	Doxazosin 1 mg tablet	Cardura	One	\$74
BEST BUY	Doxazosin 2 mg tablet	Generic	One	\$8 💲
	Doxazosin 2 mg tablet	Cardura	One	\$75
BEST BUY	Doxazosin 4 mg tablet	Generic	One	\$7 💲
	Doxazosin 4 mg tablet	Cardura	One	\$74
BEST BUY	Doxazosin 8 mg tablet	Generic	One	\$7 💲
	Doxazosin 8 mg tablet	Cardura	One	\$73
	Doxazosin 4 mg sustained-release tablet	Cardura XL	One	\$81
	Doxazosin 8 mg sustained-release tablet	Cardura XL	One	\$86
	Prazosin 1 mg capsule	Generic	Two	\$14 💲
	Prazosin 2 mg capsule	Generic	Two	\$16 🔰
	Prazosin 5 mg capsule	Generic	Two	\$20 💲
	Silodosin 4 mg capsule	Rapaflo	One	\$163
	Silodosin 8 mg capsule	Rapaflo	One	\$159
	Tamsulosin continuous-delivery capsule 0.4 mg	Generic	One	\$78
	Tamsulosin continuous-delivery capsule 0.4 mg	Flomax	One	\$183
	Terazosin 1 mg capsule	Generic	One	\$26 🔰
	Terazosin 2 mg capsule	Generic	One	\$24 💲
	Terazosin 5 mg capsule	Generic	One	\$24 💲
	Terazosin 10 mg capsule	Generic	One	\$29 💲
	5-alpha-reductase inhibitors			
	Dutasteride 0.5 mg capsule	Avodart	One	\$146
	Finasteride 5 mg tablet	Generic	One	\$75
	Finasteride 5 mg tablet	Proscar	One	\$134

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

2. As typically prescribed.

3. Prices reflect nationwide retail average for March 2012, 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 Pharma Solutions, which is not involved in our analysis or recommendations. We omit drugs with a low number of prescriptions (less than 20) because the prices are unreliable and these medications might be difficult to find because pharmacies often won't stock drugs if there is little or no demand for them.

### **Talking With Your Doctor**

The information we present here is not meant to substitute for a doctor's judgment. But we hope it will help you and your doctor arrive at a decision about which medication and dose is best for you, if one is warranted at all, 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 doctor, and that studies have found that doctors do not routinely take price into account when prescribing medicines. Unless you bring it up, your doctors might assume that cost is not a factor for you.

Many people (including physicians) think that newer drugs are better. While that's a natural assumption to make, it's not necessarily true. Studies consistently find 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 safe-ty 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. So 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 them have lapsed, usually after 12 to 15 years. At that point, other companies can make and sell the drug.

Generics are 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 more than 60 percent of all prescriptions in the U.S. today are written 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:

- First, if you see several doctors, each might not be aware of medicine the others have prescribed.
- Second, since people differ in their response to medications, it's common for doctors today 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. They 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 those reasons, it's important to keep a written list of all the drugs and supplements you are taking, and periodically review it with your doctors.

And always be sure 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 may want to 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 wellconducted, 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.hsrd.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 www.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 www.CRBestBuyDrugs.org.

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#### **About Us**

Consumers Union, publisher of *Consumer Reports*<sup>®</sup> 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. Its website is www.ConsumerReports.org.

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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 www.CRBestBuyDrugs.org. We followed a rigorous editorial process to ensure that the information in this report and on the *Consumer Reports Best Buy Drugs* website is accurate and describes generally accepted clinical practices. If we find, or are alerted to, an error, we will correct it as quickly as possible. But *Consumer Reports* and its authors, editors, publishers, licenses, and suppliers cannot be responsible for medical errors or omissions, or any consequences from the use of the information on this site. Please refer to our user agreement at www.CRBestBuyDrugs.org for further information.

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#### References

Abrams P, Chapple C, Khoury S, Roehrborn C, de la Rosette J. Evaluation and treatment of lower urinary tract symptoms in older men. *J Urol*, April 1, 2009;181(4):1779-87.

Barkin J, Roehrborn C, Siami P, Haillot O, Morrill B, Black L, et al. Effect of dutasteride, tamsulosin and the combination on patient-reported quality of life and treatment satisfaction in men with moderate-to-severe benign prostatic hyperplasia: 2-year data from the CombAT trial. *BJU Int*, April 1, 2009;103(7):919-26.

Droller MJ. A guideline for discussion and some thoughts. J Urol, 2009;181(4):1530-1.

Helfand M, Muzyk T, Garzatto M. Benign prostatic hyperplasia (BPH). Management in primary care–screening and therapy. Department of Veterans Affairs, Health Services Research & Development Service, Evidence Synthesis Pilot Program. February 2007.

Kaplan S, Roehrborn C, Meehan A, Liu K, Carides A, Binkowitz B, et al. PCPT: Evidence that finasteride reduces risk of most frequently detected intermediate- and high-grade (Gleason Score 6 and 7) cancer. *J Urol*, March 26, 2009.

Kramer BS, Hagerty KL, Justman S, Somerfield MR, Albertsen PC, Blot WJ, et al. Use of 5-{alpha}-reductase inhibitors for prostate cancer chemoprevention: American Society of Clinical Oncology/American Urological Association 2008 Clinical Practice Guideline. *J Clin Oncol*, March 20, 2009;27(9):1502-16. Kupelian V, Wei JT, O'Leary MP, Kusek JW, Litman HJ, Link CL, et al. Prevalence of lower urinary tract symptoms and effect on quality of life in a racially and ethnically diverse random sample: The Boston Area Community Health (BACH) survey. *Arch Intern Med*, November 27, 2006;166(21):2381-7.

McConnell JD, Roehrborn CG, Bautista OM, Andriole GL, Jr., Dixon CM, Kusek JW, et al. The Long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *N Engl J Med*, December 18, 2003;349(25):2387-98.

Wilt T, Brawer M, Barry M, Jones K, Kwon Y, Gingrich J, et al. The Prostate Cancer Intervention Versus Observation Trial: VA/NCI/AHRQ Cooperative Studies Program #407 (PIVOT): design and baseline results of a randomized controlled trial comparing radical prostatectomy to watchful waiting for men with clinically localized prostate cancer. *Contemp Clin Trials*, January 1, 2009;30(1):81-7.

Wilt TJ, N'Dow J. Benign prostatic hyperplasia. Part 1-Diagnosis. BMJ, January 19, 2008;336(7636):146-9.

Wilt TJ, N'Dow J. Benign prostatic hyperplasia. Part 2-Management. BMJ, January 26, 2008;336(7637):206-10.