

Patient Information

AVODART™ (dutasteride) Soft Gelatin Capsules

AVODART is for use by men only.

Read this information carefully before you start taking AVODART. Read the information you get with AVODART each time you refill your prescription. There may be new information. This information does not take the place of talking with your doctor.

What is AVODART?

AVODART is a medication for the treatment of symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate to:

- Improve symptoms
- Reduce the risk of acute urinary retention (a complete blockage of urine flow)
- Reduce the risk of the need for BPH-related surgery

AVODART is not a treatment for prostate cancer. See the end of this leaflet for information about how AVODART works.

Who should NOT take AVODART?

- Women and children should not take AVODART. A woman who is pregnant or capable of becoming pregnant should not handle AVODART capsules. See “**What are the special warnings for women about AVODART?**”
- Do not take AVODART if you have had an allergic reaction to AVODART or any of its ingredients.

What are the special warnings for women about AVODART?

- Women should never take AVODART.
- Women who are pregnant or may become pregnant should not handle AVODART Capsules. If a woman who is pregnant with a male baby gets enough AVODART into her body after swallowing it or through her skin after handling it, the male baby may be born with abnormal sex organs.

What are the special precautions about AVODART?

- Men treated with AVODART should not donate blood until at least 6 months after their final dose to prevent giving AVODART to a pregnant female through a blood transfusion.
- Tell your doctor if you have liver problems. AVODART may not be right for you.

How should I take AVODART?

- Take 1 AVODART capsule once a day.
- Swallow the capsule whole.
- You can take AVODART with or without food.

- If you miss a dose, you may take it later that day. Do not make up the missed dose by taking 2 doses the next day.
- You may find it helpful to take AVODART at the same time every day to help you remember to take your dose.

What are the possible side effects of AVODART?

Side effects seen in clinical trials with AVODART were impotence (trouble getting or keeping an erection), a decrease in libido (sex drive), enlarged breasts, and a decrease in the amount of semen released during sex. These events occurred infrequently.

Talk with your doctor if you have questions about these and other side effects that you think may be related to taking AVODART.

How should I store AVODART?

AVODART is a soft gelatin capsule that may become soft and leak or may stick to other capsules if kept at high temperatures. Store AVODART capsules at room temperature of 77°F (25°C) or lower.

If your capsules are cracked or leaking, don't use them, and contact your pharmacist.

General information about AVODART.

- Do not use AVODART for a condition for which it was not prescribed.
- Do not share your AVODART.
- Ask your doctor about how often you should return for a visit to check your BPH.
- A blood test called PSA (prostate-specific antigen) is sometimes used to detect prostate cancer. AVODART will reduce the amount of PSA measured in your blood. Your doctor is aware of this effect and can still use PSA to detect prostate cancer in you.
- If you have questions about AVODART, ask your doctor or pharmacist. They can show you detailed information about AVODART that was written for healthcare professionals.

How does AVODART work?

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). AVODART lowers DHT production in the body, leading to shrinkage of the enlarged prostate in most men. Just as your prostate became large over a long period of time, reducing the size of your prostate and improving your symptoms will take time. While some men have fewer problems and symptoms after 3 months of treatment with AVODART, a treatment period of at least 6 months is usually necessary to see if AVODART will work for you. Studies have shown that treatment with AVODART for 2 years reduces the risk of complete blockage of urine flow (acute urinary retention) and/or the need for surgery for benign prostatic hyperplasia.



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