

Start with

Avodart®

dutasteride
plus tamsulosin

A combined step in BPH management¹

For patients bothered by BPH symptoms onwards¹



Abbreviated PI for AVODART

Each capsule for oral use contains 0.5 mg dutasteride

Indication: AVODART and AVODART in combination with the alpha-blocker tamsulosin, treats and prevents progression of benign prostatic hyperplasia (BPH) by relieving prostate size, relieving symptoms, improving urinary flow and reducing the risk of acute urinary retention (AUR) and the need for BPH-related surgery.

Coverage and Administration: The recommended dose of AVODART is one capsule (0.5 mg) taken orally (the inactive vehicle capsule and not chewed or opened) once a day. Treatment for at least 6 months may be necessary in order to assess objectively whether a satisfactory response to the treatment can be achieved. For treatment of BPH, AVODART can be administered alone or in combination with the alpha-blocker tamsulosin (0.1 mg).

Renal impairment: No adjustment in dosage is anticipated for patients with renal impairment.

Hepatic impairment: The effect on dutasteride pharmacokinetics has not been studied.

Contraindications: In patients with known hypersensitivity to dutasteride, other 5-alpha reductase inhibitors, or any component of the preparation and contraindicated for use in women and children.

Warnings and Precautions:

Dutasteride is absorbed through the skin, women and children must avoid contact with treated capsules. Caution should be used in the administration of dutasteride to patients with liver disease.

Combination: Therapy with Tamsulosin and dutasteride.

In two 8-year clinical studies, the incidence of cardiac failure was higher among subjects taking the combination of AVODART and an alpha-blocker, primarily tamsulosin, than it was among subjects not taking the combination. The incidence of cardiac failure was low (1.5%), similar between the studies and no individual was observed. The incidence of cardiovascular adverse events overall in either trial. No causal relationship between AVODART alone or with an alpha-blocker and cardiac failure has been established.

Digital rectal examination: as well as other investigations for prostate cancer, should be performed on patients prior to initiating therapy with dutasteride and particularly AVODART, causes a decrease in mean serum prostate specific antigen (PSA) levels by approximately 50% after 6 months of treatment. Patients should have a new PSA baseline established after 6 months of treatment. It is recommended to monitor PSA values regularly thereafter. Any confirmed increase from lowest PSA level while on AVODART may signal the presence of prostate cancer (particularly high-grade cancer) or non-prostatic and should be carefully evaluated, even if these values are still within the normal range for men not taking a 5-alpha reductase inhibitor. In the interpretation of

a PSA value for a patient taking AVODART, previous PSA values should be sought for comparison.

Treatment with AVODART does not interfere with the use of PSA as a tool to assist in the diagnosis of prostate cancer after a new baseline has been established. Total serum PSA levels return to baseline within 6 months of discontinuing treatment. The rate of rise in total PSA remains constant even under the influence of AVODART. It is recommended to use previous PSA values as an aid in the diagnosis of prostate cancer in men undergoing dutasteride therapy. No adjustment in PSA values is necessary.

Prostate cancer and high-grade tumors: In a 4-year study (the PROUD study), 1,317 men were diagnosed with prostate cancer. There was a higher incidence of Gleason 8-10 prostate cancers in the AVODART group (n=24, 3.9%) compared to the placebo group (n=19, 3.1%). There was no increased incidence in Gleason 5-7 or 7-10 prostate cancers. No causal relationship between AVODART and high-grade prostate cancer has been established. The clinical significance of the numerical increase in Gleason 8-10 prostate cancers is unclear. AVODART should be regularly evaluated for prostate cancer risk including PSA testing.

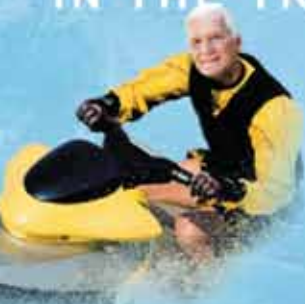
Prostate cancer: men have reported an increase in PSA levels in clinical trials and during the post-marketing period. Physicians should inform their patients to promptly report any changes in their breast tissue such as lumps or nipple discharge. It is not clear if there is a causal relationship between the occurrence of male breast cancer and long-term use of dutasteride.

Interaction: In a drug interaction study, dutasteride is metabolized by human cytochrome P450 isoenzymes CYP3A4, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, CYP3A5, CYP3A7, CYP3A9, CYP3A10, CYP3A11, CYP3A12, CYP3A13, CYP3A14, CYP3A15, CYP3A16, CYP3A17, CYP3A18, CYP3A19, CYP3A20, CYP3A21, CYP3A22, CYP3A23, CYP3A24, CYP3A25, CYP3A26, CYP3A27, CYP3A28, CYP3A29, CYP3A30, CYP3A31, CYP3A32, CYP3A33, CYP3A34, CYP3A35, CYP3A36, CYP3A37, CYP3A38, CYP3A39, CYP3A40, CYP3A41, CYP3A42, CYP3A43, CYP3A44, CYP3A45, CYP3A46, CYP3A47, CYP3A48, CYP3A49, CYP3A50, CYP3A51, CYP3A52, CYP3A53, CYP3A54, CYP3A55, CYP3A56, CYP3A57, CYP3A58, CYP3A59, CYP3A60, CYP3A61, CYP3A62, CYP3A63, CYP3A64, CYP3A65, CYP3A66, CYP3A67, CYP3A68, CYP3A69, CYP3A70, CYP3A71, CYP3A72, CYP3A73, CYP3A74, CYP3A75, CYP3A76, CYP3A77, CYP3A78, CYP3A79, CYP3A80, CYP3A81, CYP3A82, CYP3A83, CYP3A84, CYP3A85, CYP3A86, CYP3A87, CYP3A88, CYP3A89, CYP3A90, CYP3A91, CYP3A92, CYP3A93, CYP3A94, CYP3A95, CYP3A96, CYP3A97, CYP3A98, CYP3A99, CYP3A100, 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Urief™

TABLETS
SILODOSIN 4 mg

IN THE TREATMENT OF SYMPTOMATIC BPH



SPEED MATTERS^{1,2}

RAPID SYMPTOM RELIEF FROM THE START



SUSTAINED SYMPTOM RELIEF²¹

MADE SIMPLE

SAFETY

THAT KEEPS HIM GOING



SELECTIVITY

THAT TARGETS THE PROSTATE

Eisai Co., Ltd.
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TH-UR-CH-14A-02
ใบอนุญาตโฆษณาเลขที่ ๒๓. 680/2557



เป็นยาใหม่ใช้เฉพาะสถานพยาบาล
แพทย์ควรติดตามผลการรักษา

hke



Further information is available on request.
โปรดอ่านรายละเอียดเพิ่มเติม
ในเอกสารอ้างอิงฉบับสมบูรณ์และเอกสารกำกับยา
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