In clinical trials, dutasteride reduced serum PSA concentration by approximately 50% within 3 to 6 months of treatment.

Warfarin:

Alpha adrenergic antagonists and PDE-5 inhibitors are both vasodilators that can lower blood pressure. Concomitant products, including dutasteride and tamsulosin hydrochloride capsules, are coadministered with PDE-5 inhibitors.

Full prescribing information includes:

- Indications and Usage
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Clinical Pharmacology
- How Supplied/Storage and Handling
- References

Read this patient information before you start taking dutasteride and tamsulosin hydrochloride capsules. Call your healthcare provider if:

- You are taking another medicine with tamsulosin hydrochloride capsules. See Warnings and Precautions (5.2) and Clinical Pharmacology (12.3).
- You are taking another medicine with tamsulosin hydrochloride capsules. See Warnings and Precautions (5.2) and Clinical Pharmacology (12.3).

Dutasteride and tamsulosin hydrochloride capsules are a prescription medicine that contains 2 medicines: dutasteride and tamsulosin. Dutasteride and tamsulosin hydrochloride capsules are used to treat the symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

Who should not take dutasteride and tamsulosin hydrochloride capsules if you are:

- Pregnant or breastfeeding. Dutasteride and tamsulosin hydrochloride capsules may harm your unborn baby. Pregnant women should not take dutasteride and tamsulosin hydrochloride capsules if you are pregnant or could become pregnant. Women should not handle dutasteride and tamsulosin hydrochloride capsules if you are pregnant or could become pregnant. Dutasteride and tamsulosin hydrochloride capsules may cause harm to your unborn baby. Women who are pregnant or could become pregnant should not handle dutasteride and tamsulosin hydrochloride capsules if you are pregnant or could become pregnant. If the medicine is swallowed by anyone, call your local poison control center or seek immediate medical attention.

Dutasteride and tamsulosin hydrochloride capsules may cause serious side effects when taken together.

- Decreased blood pressure. Dutasteride and tamsulosin hydrochloride capsules may cause serious side effects when taken together.
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The maximum effect of daily doses of dutasteride is rarely seen. A 2-year carcinogenicity study was conducted in B6C3F1 mice at doses of 3, 35, 250, and 500 mg/kg/day (to a maximum of 25°C (68° to 77°F) [see USP Controlled Room Temperature].

The most common side effects of dutasteride and tamsulosin hydrochloride capsules include:

- impotence* (in men only)
- reduced sexual desire
- nausea
- diarrhea
- dizziness
- enlarged or painful breasts
- decreased sperm counts
- low sperm counts
- feeling short of breath
- breathlessness
- fatigue
- back pain
- cold or flulike symptoms
- shivers
- muscle aches
- rash
- urination problems
- weakness
- chills
- nosebleeds
- shortness of breath
- loss of appetite
- sweating
- joint pain
- mental health problems, including behavior changes and depression

Dutasteride, an ingredient of dutasteride and tamsulosin hydrochloride capsules, has been shown to reduce sperm counts, semen volume, and sperm movement. However, the effect of dutasteride and tamsulosin hydrochloride capsules on male fertility is not known.

Prostate-Specific Antigen (PSA) Test: Your healthcare provider may check you for prostate problems, including prostate cancer before you start and while you take dutasteride and tamsulosin hydrochloride capsules. A blood test called PSA (prostate-specific antigen) is often used to check for prostate cancer. Dutasteride and tamsulosin hydrochloride capsules will reduce the amount of PSA measured in your blood. Your healthcare provider is aware of this effect and can still use PSA to see if you might have prostate cancer, increases in your PSA levels while on treatment with dutasteride and tamsulosin hydrochloride capsules that are not due to prostate cancer, or decreases in PSA levels that are in the normal range should be evaluated by your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of dutasteride and tamsulosin hydrochloride capsules. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I take dutasteride and tamsulosin hydrochloride capsules?

Store dutasteride and tamsulosin hydrochloride capsules at 20°C to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dutasteride and tamsulosin hydrochloride capsules may become deformed and/or discolored if kept at high temperatures.

Do not use or touch dutasteride and tamsulosin hydrochloride capsules if they are deformed, discolored, or if you notice precipitation.

Safety: throw away medication that is no longer needed.

Keep dutasteride and tamsulosin hydrochloride capsules and all medicines out of the reach of children.

Medications are sometimes prescribed for purposes other than the ones listed in a说明书. Do not use dutasteride and tamsulosin hydrochloride capsules for other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about dutasteride and tamsulosin hydrochloride capsules. It does not cover all possible side effects or interactions.

What are the ingredients in dutasteride and tamsulosin hydrochloride capsules?

Active ingredients: dutasteride and tamsulosin hydrochloride

Inactive ingredients: butylated hydroxyisobutyrate, ethylcellulose, gelatin, glycol, hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose monohydrate, polyethylene glycol, polyvinyl alcohol, sodium lauryl sulfate, sodium metasilicate, t疏o sodium, triethyl citrate, and USP purified water.

How do dutasteride and tamsulosin hydrochloride capsules work?

Dutasteride and tamsulosin hydrochloride capsules contain 2 medications: dutasteride and tamsulosin. These 2 medications work in different ways to improve symptoms of BPH. Dutasteride shrinks the enlarged prostate and tamsulosin relaxes muscles in the prostate and bladder neck. Together, these effects help relieve symptoms of BPH. These 2 medications, when used together, can improve symptoms of BPH better than either medication when used alone.

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Par Pharmaceutical Companies, Inc.

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