

Dutasteride/Tamsulosin Sandoz® 500/400

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Dutasteride/Tamsulosin Sandoz?

Dutasteride/Tamsulosin Sandoz contains the active ingredients dutasteride and tamsulosin hydrochloride.

Dutasteride/Tamsulosin Sandoz is used in men who benign prostatic hyperplasia (BPH).

For more information, see Section [1. Why am I using Dutasteride/Tamsulosin Sandoz?](#) in the full CMI.

2. What should I know before I use Dutasteride/Tamsulosin Sandoz?

Do not use if you have ever had an allergic reaction to Dutasteride/Tamsulosin Sandoz, any other 5-alpha reductase inhibitors or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines. Talk to your doctor if your partner is pregnant or plans to become pregnant or is breastfeeding.

For more information, see Section [2. What should I know before I use Dutasteride/Tamsulosin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dutasteride/Tamsulosin Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Dutasteride/Tamsulosin Sandoz?

- The usual dosage is one capsule once per day.
- Take your medicine approximately 30 minutes after the same meal each day. Do not take Dutasteride/Tamsulosin Sandoz on an empty stomach.

More instructions can be found in Section [4. How do I use Dutasteride/Tamsulosin Sandoz?](#) in the full CMI.

5. What should I know while using Dutasteride/Tamsulosin Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Dutasteride/Tamsulosin Sandoz.• If you are having a blood test remind your doctor that you are taking Dutasteride/Tamsulosin Sandoz.• If you are having cataract surgery, tell your surgeon that you are taking Dutasteride/Tamsulosin Sandoz.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose.• Do not donate blood whilst taking Dutasteride/Tamsulosin Sandoz or for 6 months after stopping treatment.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how this medicine affects you.• Dutasteride/Tamsulosin Sandoz can cause dizziness, light-headedness and potential fainting due to a sudden drop in blood pressure upon standing up (orthostatic hypotension).
Looking after your medicine	<ul style="list-style-type: none">• Keep Dutasteride/Tamsulosin Sandoz in a cool, dry place where it stays below 30°C.

For more information, see Section [5. What should I know while using Dutasteride/Tamsulosin Sandoz?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported include impotence (an inability to maintain an erection), decrease in libido (sex drive), difficulty with ejaculation, breast swelling or tenderness, difficulty in sleeping (insomnia), dizziness, constipation, diarrhoea, vomiting, a fast heart beat, feeling weak or a loss of strength, low blood pressure upon standing up, itchy, blocked or runny nose and allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Dutasteride/Tamsulosin Sandoz® 500/400

Active ingredient(s): *dutasteride and tamsulosin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dutasteride/Tamsulosin Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dutasteride/Tamsulosin Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Dutasteride/Tamsulosin Sandoz?](#)
- [2. What should I know before I use Dutasteride/Tamsulosin Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Dutasteride/Tamsulosin Sandoz?](#)
- [5. What should I know while using Dutasteride/Tamsulosin Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Dutasteride/Tamsulosin Sandoz ?

Dutasteride/Tamsulosin Sandoz contains the active ingredients dutasteride and tamsulosin hydrochloride.

Dutasteride belongs to a group of medicines called 5-alpha reductase enzyme inhibitors. Tamsulosin hydrochloride belongs to a group of medicines called alpha-blockers.

Dutasteride/Tamsulosin Sandoz is used in men with benign prostatic hyperplasia (BPH).

BPH is a non-cancerous enlargement of the prostate gland which is located at the lower portion of the urinary bladder surrounding the urethra (urine carrying tube). In men with BPH, the prostate gland become large enough to squeeze the urine tube running through it. If the urine tube is squeezed it narrows, making it more difficult for you to pass urine normally and you may have some or all of the following symptoms:

- difficulty in starting to urinate
- an interrupted, weak urinary stream
- more frequent urination, especially at night
- feeling that you need to urinate, right away
- leaking or dribbling
- a feeling that you cannot empty your bladder completely.

As the disease progresses, untreated BPH can lead to an increased risk of complete blockage of urine flow (acute urinary retention) and/or the need for surgery.

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). The dutasteride component of Dutasteride/Tamsulosin Sandoz lowers DHT production in the body, leading to shrinkage of the enlarged prostate in most men. The tamsulosin

hydrochloride component of Dutasteride/Tamsulosin Sandoz acts by relaxing the smooth muscle in your prostate gland, making it easier to pass urine.

Just as your prostate became large over a long period of time, reducing the size of your prostate and improving your symptoms may take time.

Your doctor may have prescribed Dutasteride/Tamsulosin Sandoz for another reason. Ask your doctor if you are unsure why Dutasteride/Tamsulosin Sandoz was prescribed for you.

Dutasteride/Tamsulosin Sandoz is not addictive.

2. What should I know before I use Dutasteride/Tamsulosin Sandoz?

Warnings

Do not use Dutasteride/Tamsulosin Sandoz if:

- you are allergic to dutasteride, tamsulosin hydrochloride or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other 5-alpha reductase enzyme inhibitors
- you are a woman or child
- you have a history of sudden drop in blood pressure upon standing up (known as orthostatic hypotension)
- you have liver or kidney disease
- you are taking other medications that relax the smooth muscle of blood vessels (e.g. Flomaxtra, Minipress)
- the expiry date (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions
- suffer from any liver or kidney conditions
- are going to have cataract surgery
- are taking any medicines to lower your blood pressure (alpha blocker medicines that relax the smooth muscles within blood vessels)
- are taking an antifungal medicine (e.g. ketoconazole)
- you have an allergy to sulfur
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if your partner is pregnant or intends to become pregnant or is breastfeeding.

Women who are pregnant or may be pregnant, and children, must avoid handling punctured or leaking capsules. If skin contact occurs wash the affected area immediately with soap and water.

If dutasteride is absorbed through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the genital organs.

Dutasteride has been found in the semen of men taking dutasteride. If your partner is or may be pregnant, you must avoid exposing her to your semen as dutasteride may affect the normal development of a male baby. **You must use a barrier form of contraception.**

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are allergic to any foods, dyes, preservatives or any other medicines.

Some medicines may interfere with Dutasteride/Tamsulosin Sandoz and affect how it works.

- long-term combination of dutasteride with medicines that are potent inhibitors of the enzyme CYP3A4 (e.g. ritonavir, indinavir, nefazodone, itraconazole, ketoconazole) may increase the concentration of dutasteride in the blood
- antifungal medicines such as ketoconazole can lead to an increase in the concentration of tamsulosin hydrochloride in the blood
- antidepressants known as selective serotonin reuptake inhibitors (e.g. paroxetine) can lead to an increase in the concentration of tamsulosin hydrochloride in the blood.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dutasteride/Tamsulosin Sandoz.

4. How do I use Dutasteride/Tamsulosin Sandoz?

How much to take

- The usual dose is one capsule daily.
- Follow the instructions provided and use Dutasteride/Tamsulosin Sandoz until your doctor tells you to stop.

When to take Dutasteride/Tamsulosin Sandoz

- Dutasteride/Tamsulosin Sandoz should be taken approximately 30 minutes after the same meal each day. Do not take this medicine on an empty stomach.
- Swallow your capsule whole with some water.
- Do not crush or chew the capsules. The contents of the capsule may make your mouth or throat sore.

If you forget to use Dutasteride/Tamsulosin Sandoz

Dutasteride/Tamsulosin Sandoz should be taken at the same time each day.

If you forget to take Dutasteride/Tamsulosin Sandoz skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Dutasteride/Tamsulosin Sandoz

If you think that you have used too much Dutasteride/Tamsulosin Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Dutasteride/Tamsulosin Sandoz?

Things you should do

Tell your doctor if you:

- have not taken Dutasteride/Tamsulosin Sandoz exactly as directed
- are having a blood test, tell your doctor you are taking Dutasteride/Tamsulosin Sandoz as this medicine decreases your prostate-specific antigen (PSA) levels. The PSA test helps your doctor to tell if you have prostate disease, including prostate cancer. If you have a higher than normal amount of PSA in your blood it could mean that you have a higher risk of prostate cancer. Men taking Dutasteride/Tamsulosin Sandoz should have their PSA measured 6 months after starting treatment and then regularly after that. You could still be at risk for prostate cancer even though your PSA is lower. Your doctor can still use PSA to help detect prostate cancer, by comparing your test results each time you have a PSA test.

Remind any doctor, dentist or pharmacist you visit that you are using Dutasteride/Tamsulosin Sandoz.

Things to be careful of

If you are having a cataract operation and are already taking or have taken Dutasteride/Tamsulosin Sandoz, the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the operation (floppy iris syndrome). This can be managed if your surgeon knows that you are taking Dutasteride/Tamsulosin Sandoz before you have the operation. If you are going to have eye

surgery tell your surgeon that you are taking or have taken Dutasteride/Tamsulosin Sandoz.

In a clinical study of men at increased risk of developing prostate cancer, a serious form of prostate cancer was reported more often in men taking dutasteride and tamsulosin hydrochloride than men who did not take dutasteride and tamsulosin hydrochloride. The reasons for this is currently unknown but may be due to the design of the clinical study.

Be careful if you are switching from another tamsulosin containing medicine to Dutasteride/Tamsulosin Sandoz as you may experience dizziness or light headedness when standing up.

If you feel dizzy or lightheaded at any time whilst taking Dutasteride/Tamsulosin Sandoz, sit or lie down until the symptoms pass.

Things you should not do

- Do not stop using this medicine suddenly or change the dose.
Some men notice an early improvement in their symptoms however others may need to continue treatment for 3 to 6 months to see if Dutasteride/Tamsulosin Sandoz works for them. Continue to take this medicine as your symptoms improve.
If you do not take your medicine as directed it may interfere with your doctor's ability to monitor your PSA levels.
- Do not donate blood whilst taking Dutasteride/Tamsulosin Sandoz or for 6 months after you stop treatment.
- Do not give this medicine to anyone else even if they have similar symptoms to you.
- Do not use this medicine to treat any other complaints.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dutasteride/Tamsulosin Sandoz affects you.

Dutasteride/Tamsulosin Sandoz may cause some people to experience dizziness or light headedness.

Looking after your medicine

- Keep Dutasteride/Tamsulosin Sandoz in a cool, dry place where it stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • impotence (inability to maintain an erection) • decrease in libido (sex drive) • difficulty with ejaculation or retrograde ejaculation (where the ejaculate goes back into the bladder instead of being squirted out) • decrease in semen volume • difficulty in sleeping (insomnia) • dizziness • constipation • diarrhoea • vomiting • fast heart beat • weakness or loss of strength • hair loss (usually from the body) or hair growth • fainting • changes in your mood, feeling depressed • itchy, blocked or runny nose • changes in your vision • nose bleeds • dry mouth 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • allergic reaction – signs include wheezing, difficulty breathing, swelling of the lips or mouth, a rash or hives on the skin and fainting • breast swelling or tenderness. If this becomes troublesome or you notice breast lumps or nipple discharge talk to your doctor about these changes as they could be signs of a serious condition such as breast cancer 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> serious skin reactions with a widespread rash, blisters and peeling skin particularly around the mouth, nose, eyes and genitals (such as Stevens-Johnson syndrome) testicular pain and/or swelling low blood pressure upon standing up (orthostatic hypotension). Take care when moving from a lying or sitting position to a standing position prolonged erection unrelated to sexual activity 	
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	<ul style="list-style-type: none"> purified water
Potential allergens	lecithin (soya bean product)

Do not take this medicine if you are allergic to any of these ingredients.

What Dutasteride/Tamsulosin Sandoz looks like

Dutasteride/Tamsulosin Sandoz 500/400 – oblong, hard-shell capsules with a brown body and an orange cap [each containing one oblong, opaque, dull-yellow dutasteride soft gelatin capsule (500 µg dutasteride) and white to off-white tamsulosin hydrochloride pellets (400 µg tamsulosin hydrochloride)]. Pack size of 30 or 90 capsules (Aust R 362953).

Not all pack sizes may be marketed in Australia.

Who distributes Dutasteride/Tamsulosin Sandoz

Sandoz Pty Ltd
100 Pacific Highways
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dutasteride/Tamsulosin Sandoz contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> dutasteride 500 µg tamsulosin hydrochloride 400 µg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> butylated hydroxytoluene carrageenan microcrystalline cellulose gelatin glycerol glyceryl caprylate/caprates magnesium stearate hypromellose iron oxide red iron oxide yellow lecithin medium chain triglycerides ethyl acrylate copolymer (1:1) methacrylic acid sodium hydroxide triacetin potassium chloride sunset yellow FCF purified talc titanium dioxide