# DOUBLUTS

## 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 taking DOUBLUTS?

DOUBLUTS contains the active ingredients dutasteride and tamsulosin hydrochloride. DOUBLUTS is used in men who have benign prostatic hyperplasia (BPH).

For more information, see Section 1. Why am I taking DOUBLUTS? in the full CMI.

## 2. What should I know before I take DOUBLUTS?

Do not use if you have ever had an allergic reaction to dutasteride, tamsulosin hydrochloride, 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 take DOUBLUTS? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with DOUBLUTS 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 take DOUBLUTS?

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

More instructions can be found in Section 4. How do I take DOUBLUTS? in the full CMI.

## 5. What should I know while taking DOUBLUTS?

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|---|---|
| **Things you should do** | • Remind any doctor, dentist or pharmacist you visit that you are taking DOUBLUTS.<br>• If you are having a blood test, remind your doctor that you are taking DOUBLUTS.<br>• If you are having cataract surgery, tell your surgeon that you are taking DOUBLUTS. |
| **Things you should not do** | • Do not stop using this medicine suddenly or change the dose.<br>• Do not donate blood while taking DOUBLUTS or for 6 months after stopping treatment. |
| **Driving or using machines** | • Do not drive or operate machinery until you know how this medicine affects you.<br>• DOUBLUTS 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** | • Store your capsules in the bottle until it is time to take them.<br>• Store capsules below 25°C. |

For more information, see Section 5. What should I know while taking DOUBLUTS? 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, skin rash, vomiting, a fast heartbeat, feeling weak or a loss of strength, low blood pressure upon standing up, itchy, blocked or runny nose, suicidal thoughts 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.

# DOUBLUTS

**Active ingredient(s):** *dutasteride 500 micrograms and tamsulosin hydrochloride 400 micrograms*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DOUBLUTS. **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 DOUBLUTS.**

**Where to find information in this leaflet:**


1. Why am I taking DOUBLUTS?
2. What should I know before I take DOUBLUTS?
3. What if I am taking other medicines?
4. How do I take DOUBLUTS?
5. What should I know while taking DOUBLUTS?
6. Are there any side effects?
7. Product details


## 1. Why am I taking DOUBLUTS?

**DOUBLUTS 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.

**DOUBLUTS is used in men with benign prostatic hyperplasia (BPH).**

BPH is a non-cancerous enlargement of the prostate gland which is located in the lower portion of the urinary bladder surrounding the urethra (urine carrying tube). In men with BPH, the prostate gland becomes large enough to squeeze the urine tube running through it. If this tube is squeezed it narrows, making it more difficult to pass urine 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 DOUBLUTS lowers DHT production in the body leading to a shrinkage of the enlarged prostate in most men. The tamsulosin hydrochloride component of DOUBLUTS acts by relaxing the smooth muscle in your prostate gland making it easier to pass urine.

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

Your doctor may have prescribed DOUBLUTS for another reason. Ask your doctor if you are unsure why DOUBLUTS was prescribed for you.

DOUBLUTS is not addictive.

## 2. What should I know before I take DOUBLUTS?

### Warnings

### Do not use DOUBLUTS 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 a sudden drop in blood pressure upon standing up (known as orthostatic hypotension).
- 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 or disease.
- are going to have cataract (cloudy lens) 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 sulphur.
- 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 area straight away 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 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 DOUBLUTS and affect how it works.**

**These medicines include:**

- long-term combination of dutasteride with medicines that are potent inhibitors of the enzyme CYP3A4 (e.g. ritonavir, indinavir, nefazodone, itraconzole, 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 DOUBLUTS.**

## 4. How do I take DOUBLUTS?

### How much to take

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

### When to take DOUBLUTS

- DOUBLUTS 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 take DOUBLUTS

DOUBLUTS should be taken at the same time each day.

**If you forget to take DOUBLUTS 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 take too much DOUBLUTS

If you think that you have used too much DOUBLUTS, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), 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 taking DOUBLUTS?

### Things you should do

### Tell your doctor if you:

- have not taken DOUBLUTS exactly as directed.
- are having a blood test and you are taking DOUBLUTS 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 DOUBLUTS 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 taking DOUBLUTS.

### Things to be careful of

If you are having a cataract operation and are taking or have previously taken DOUBLUTS, 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 DOUBLUTS before you have the operation. If you are going to have eye surgery, tell your surgeon that you are taking or have taken DOUBLUTS.

In a clinical study of men at increased risk of developing prostate cancer, men taking dutasteride had reported a serious form of prostate cancer more often than men who did not take dutasteride. However, no causal relationship between dutasteride and high-grade prostate cancer has been established.

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

If you feel dizzy or lightheaded at any time while taking DOUBLUTS, 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 DOUBLUTS 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 while taking DOUBLUTS 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 DOUBLUTS affects you.**

DOUBLUTS may cause some people to experience dizziness or light headedness.

### Looking after your medicine

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

Store it in a cool dry place (below 25ºC) 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.

Store your capsules in the bottle until it is time to take them.

**Keep it where young children cannot reach it.**

### 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.

In clinical studies where patients were taking both dutasteride and an alpha-blocker, the rate of heart failure (meaning your heart does not pump blood as well as it should) was higher than in patients taking only dutasteride or only an alpha-blocker. However, this was seen in less than 1% of patients.

If you are taking DOUBLUTS, talk to your doctor about this and other possible side effects.

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 |
|---|---|
| **Gastrointestinal disorders:**<br>• constipation<br>• diarrhoea<br>• vomiting<br>• dry mouth<br>**Cardiovascular disorders:**<br>• fast heartbeat<br>**Psychiatric disorders:**<br>• difficulty in sleeping (insomnia)<br>• changes in your mood, feeling depressed<br>• decrease in libido (sex drive)<br>**Reproductive system and breast disorders:**<br>• impotence (inability to maintain an erection)<br>• difficulty with ejaculation or retrograde ejaculation (where the ejaculate goes back into the bladder instead of being squirted out)<br>• decrease in semen volume<br>**Nervous system disorders:**<br>• dizziness<br>• fainting<br>**General disorders:**<br>• weakness or loss of strength<br>**Skin and subcutaneous tissue disorders:**<br>• hair loss (usually from the body) or hair growth<br>• a red, itchy, scaly rash with small blisters and bumps under the skin (dermatitis exfoliative)<br>**Respiratory, thoracic, and mediastinal disorders:**<br>• itchy, blocked or runny nose<br>• nose bleeds<br>**Eye disorders:**<br>• changes in your vision | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

### Serious side effects

| Serious side effects | What to do |
|---|---|
| **Allergic reaction:**<br>• signs include wheezing, difficulty breathing, swelling of the lips or mouth, itching, a rash or hives on the skin and fainting<br>**Skin and subcutaneous tissue disorders:**<br>• serious skin reactions with a widespread rash, blisters and peeling skin particularly around the mouth, nose, eyes and | **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.** |

| | |
|---|---|
| genitals (such as Stevens-Johnson syndrome)<br>• skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)<br>**Reproductive system and breast disorders:**<br>• breast swelling or tenderness. If this becomes troublesome or if 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.<br>• testicular pain and/or swelling<br>• prolonged erection unrelated to sexual activity<br>**Cardiovascular disorders:**<br>• low blood pressure upon standing up (orthostatic hypotension). Take care when moving from a lying or sitting position to a standing position.<br>**Psychiatric disorders:**<br>• suicidal thoughts have been reported in patients taking another medicine from the same therapeutic class (5-alpha reductase inhibitor) by mouth. | |

**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 DOUBLUTS contains

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|---|---|
| **Active ingredient (main ingredient)** | dutasteride<br>tamsulosin hydrochloride |
| **Other ingredients (inactive ingredients)** | butylated hydroxytoluene<br>carnauba wax<br>carrageenan<br>microcrystalline cellulose<br>gelatin<br>glycerol<br>glyceryl caprylate/caprate<br>hypromellose<br>iron oxide red<br>iron oxide yellow<br>lecithin<br>medium chain triglycerides<br>ethyl acrylate copolymer (1:1) methacrylic acid<br>potassium chloride<br>maize starch<br>sunset yellow FCF<br>purified talc<br>titanium dioxide<br>triethyl citrate<br>purified water<br>TekPrint SW-9008 Black Ink<br>TekPrint SW-9010 Black Ink |
| **Potential allergens** | Lecithin<br>The colouring agent Sunset Yellow which may cause allergic-type reactions. |

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

### What DOUBLUTS looks like

DOUBLUTS capsules are an oblong, hard-shell capsule with a brown body and an orange cap imprinted with GS 7CZ in black ink.

DOUBLUTS is available in bottles of 7, 30 or 90 capsules.

Not all pack sizes may be distributed in Australia.

AUST R 326621

### Who distributes DOUBLUTS

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford VIC 3067

Australia

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