

DUODART[®]

500 mcg/400 mcg

Dutasteride 500 mcg and tamsulosin HCl 400 mcg

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take DUODART.

This leaflet answers some common questions about DUODART. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking DUODART against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is DUODART used for?

DUODART is a combination of two medicine; dutasteride and tamsulosin hydrochloride. Dutasteride belongs to a group of medicines called 5-alpha reductase enzyme inhibitors and tamsulosin hydrochloride belongs to a group of medicines called alpha-blockers. These medicines can be used either alone or in combination in men who have a condition known as 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 becomes 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 DUODART lowers DHT production in the body, leading to shrinkage of the enlarged prostate in most men. The tamsulosin hydrochloride component of DUODART 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 DUODART for another reason. Ask your doctor if you are unsure why DUODART was prescribed for you.

DUODART is not addictive.

Before you take DUODART

Do not take if:

You must not take DUODART if:

- you have ever had an allergic reaction to dutasteride, other 5 alpha reductase enzyme inhibitors, tamsulosin hydrochloride or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- you are a woman or child.
- you have a history of orthostatic hypotension (sudden drop in blood pressure upon standing up)
- you have severe liver disease
- you have severe kidney disease
- you are taking other medication that relaxes the smooth muscle of blood vessels (some of the trade names are Flomaxtra, Minipress, Hytrin)
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you suffer from liver or kidney disease and/or other medical conditions
- you are going to have cataract (cloudy lens) surgery
- you are taking medicine to lower blood pressure (alpha blocker medicines that relax the smooth muscle of the blood vessels).
- you are taking any antifungal medicine such as ketoconazole
- you are taking any other medicines, including medicines you buy without a prescription such as vitamin supplements or herbal medicines.
- you have any allergies to sulphur

Women who are pregnant or may be pregnant, and children, must avoid handling punctured or leaking capsules. Wash the affected area immediately with soap and water if there is any contact with the skin.

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 condom during sex.

You must not donate blood until 6 months after you've stopped taking DUODART.

How do I take DUODART?

How much to take

Take DUODART as directed by your doctor or pharmacist.

The usual dose in men is one capsule daily.

How to take it

Swallow your DUODART capsules whole with some water, approximately 30 minutes after the same meal each day. It is very important that DUODART is not taken on an empty stomach as this may increase the risk of adverse effects.

Don't chew or open the capsules. Contact with the contents of the capsule may make your mouth or throat sore.

How long to take it for

It is important to continue to take DUODART for as long as your doctor prescribes it, even if you do not feel any immediate benefit. Some men notice an early improvement in their symptoms however others may need to continue for 3-6 months to see if DUODART helps them. You must also continue to take your medicine as your symptoms improve.

Do not stop taking DUODART, or change the dose without first checking with your doctor.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (in Australia call 13 11 26) for advice, if you think you or anyone else may have taken too much DUODART, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking DUODART

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

If you forget to take a capsule, don't worry, just take the next dose as normal and continue as before.

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

DUODART decreases your PSA (prostate-specific antigen) levels. Therefore, if you are having a blood test to measure your PSA levels, tell your doctor you are taking DUODART.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use DUODART to treat any other complaints unless your doctor says to.

Things to be careful of

Some patients may experience dizziness or feel light headed.

Be careful driving or operating machinery until you know how DUODART affects you.

If you are having a cataract operation and are already taking or have taken DUODART, 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 beforehand that you have taken DUODART. If you are going to have eye surgery for cataracts, please tell your surgeon that you are taking or have taken DUODART.

In clinical studies where patients were taking both the individual

components of DUODART, the rate of heart failure was higher than in patients taking the individual components alone. However, this was seen in less than 1% of patients. (Heart failure means your heart does not pump blood as well as it should.)

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

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 DUODART than men who did not take DUODART. The reasons for this is currently unknown but may be due to the design of the clinical study.

A blood test to measure the amount of a substance called PSA (prostate specific antigen) in your blood can help 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 are at a higher risk of prostate cancer.

Men taking DUODART should have their PSA measured 6 months after starting treatment and then regularly after that. Taking DUODART will reduce the amount of PSA measured in your blood. 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.

It is important to take your medicine as your doctor recommends. If you do not take it regularly it may interfere with your doctor's ability to monitor your PSA.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or

allergic reactions due to taking DUODART, even if the problem is not listed below.

Like other medicines, DUODART can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- impotence (inability to achieve or maintain an erection)
- decrease in libido (sex drive)
- difficulty with ejaculation
- breast swelling or tenderness. If this becomes troublesome or if you notice breast lumps or nipple discharge you should talk to your doctor about these changes as these may be signs of a serious condition, such as breast cancer.
- dizziness
- difficulty in sleeping (insomnia)

The following uncommon side effects have been reported:

- allergic reactions
- fast heart beat
- constipation, diarrhoea, vomiting
- weakness or loss of strength
- low blood pressure on standing
- itchy, blocked or runny nose.

Rarely, the following side effects have been reported:

- hair loss (usually from the body) or hair growth
- fainting

Very rarely, the following side effects have been reported:

- depressed mood
- serious skin reactions (such as Stevens-Johnson syndrome)
- testicular pain and testicular swelling
- nose bleeding
- changes in vision

DUODART can cause dizziness, light-headedness and on rare

occasions fainting. Take care when moving from a lying down or sitting position to sitting or standing, particularly if you wake up in the night, until you know how this medicine affects you.

There are some differences between DUODART and other tamsulosin products available in Australia. If you are switching to DUODART from another tamsulosin containing product dizziness or light headedness may occur when standing up.

If you feel dizzy or light-headed at any time during treatment, sit or lie down until the symptoms pass.

You may also experience a decrease in sperm count and semen volume.

One side effect of DUODART is known as "retrograde ejaculation". When this happens most of the ejaculation fluid runs back into the bladder instead of being squirted out. Retrograde ejaculation is painless.

Extremely rarely, medications similar to DUODART have caused prolonged painful erections, which is unrelated to sexual activity. If you have a prolonged erection, call your doctor or go to the Emergency Room as soon as possible.

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**
- **A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals. These could be the symptoms of a serious skin reaction known as Stevens-Johnson syndrome.**

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store DUODART?

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

Keep DUODART in a cool, dry place where it stays below 25°C.

Do not leave in a car, on a window sill or in a bathroom.

Keep DUODART in its bottle until it is time to take your dose.

Return any unused or expired medicine to your pharmacist.

Product description

What DUODART looks like

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

DUODART capsules are supplied in bottles of 7, 30 or 90 capsules.

Not all pack sizes may be distributed in Australia.

Ingredients

DUODART capsules contain the active ingredients:

- dutasteride 500 mcg dissolved in a liquid
- tamsulosin hydrochloride 400 mcg.

DUODART capsules also contain the inactive ingredients:

- mono-di glycerides of caprylic/capric acid
- butylated hydroxytoluene
- gelatine
- glycerol
- titanium dioxide
- cellulose, microcrystalline
- methacrylic acid
- talc
- triethyl citrate
- carrageenan

- potassium chloride
- hypromellose
- triglycerides, medium chain
- lecithin
- carnauba wax
- maize starch
- yellow iron oxide
- red iron oxide
- FD&C Yellow 6

Sponsor

DUODART is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford VIC 3067
Australia

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and books, for example in the public libraries.

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The information provided applies only to DUODART®.

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