

APO-Dutasteride

Contains the active ingredient dutasteride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about dutasteride. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-DUTASTERIDE Soft Capsules. It contains the active ingredient dutasteride.

This medicine belongs to a group of medicines called 5 alpha reductase enzyme inhibitors which are used 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.

Dutasteride may also be taken in combination with another type of medicine called an alpha blocker in order to treat symptoms of an enlarged prostate.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are a woman or child.**
- **You are hypersensitive to, or have had an allergic reaction to, dutasteride, other 5 alpha reductase enzyme inhibitors or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms. **If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You suffer from liver disease and/or other medical conditions. :
3. You are planning to have surgery or an anaesthetic.
4. You are currently receiving or are planning to receive dental treatment.
5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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 dutasteride.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Each capsule must be swallowed whole and not chewed or opened. Contact with the contents of the capsule may make your mouth or throat sore.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side

effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking dutasteride or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- impotence (inability to achieve or maintain an erection).
- decrease in libido (sex drive).
- difficulty with ejaculation.
- breast swelling or tenderness.
- dizziness when taken with an alpha blocker.
- hair loss (usually from the body) or hair growth
- depressed mood
- testicular pain and testicular swelling
- decrease in sperm count and semen volume.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to dutasteride, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-DUTASTERIDE Soft Capsules looks like

Dutasteride 500 micrograms: An oily, colourless to pale yellow liquid absent of any visible particles and/or crystals within a pale yellow, oblong gelatin capsule printed with red ink. Logo is "A 0.5".

Ingredients

Each soft capsule contains 500 micrograms of dutasteride as the active ingredient.

It also contains the following inactive ingredients:

- mono- and di- glycerides
- butylated hydroxytoluene
- gelatin
- glycerol
- water – purified
- iron oxide yellow CI77499
- titanium dioxide
- OPACODE monogramming ink S-1-15095 Red (PI#12470).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Dutasteride 500 micrograms soft capsules (blister pack 30): AUST R 212047.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO is a registered trade mark of Apotex Inc.

This leaflet was last updated in: November 2017