APO-DUTASTERIDE

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 APO-DUTASTERIDE?

APO-DUTASTERIDE contains the active ingredient dutasteride. APO-DUTASTERIDE is used in men who have benign prostatic hyperplasia (BHP).

For more information, see Section 1. Why am I using APO-DUTASTERIDE? in the full CMI.

2. What should I know before I use APO-DUTASTERIDE?

Do not use if you have ever had an allergic reaction to APO-DUTASTERIDE or any of the ingredients listed at the end of the CMI.

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

For more information, see Section 2. What should I know before I use APO-DUTASTERIDE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-DUTASTERIDE 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 APO-DUTASTERIDE?

- The usual dosage is one capsule once per day taken with or without food.
- Swallow the capsule whole with water.

More instructions can be found in Section 4. How do I use APO-DUTASTERIDE? in the full CMI.

5. What should I know while using APO-DUTASTERIDE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using APO-DUTASTERIDE. • If you are having a blood test remind your doctor that you are taking APO-DUTASTERIDE. • If you are going to have surgery or an anaesthetic or are going into hospital, tell you doctor that you are taking APO-DUTASTERIDE.
Things you should not do	• Do not stop using this medicine or change the dose. • Do not donate blood whilst taking APO-Dutasteride or 6 months after stopping treatment.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how APO-DUTASTERIDE affects you.
Looking after your medicine	• Store your capsules in the original packaging until it is time to take them. • Store your capsules below 25°C.

For more information, see Section 5. What should I know while using [insert medicine]? 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, decrease in semen volume, dizziness when taken with an alpha blocker (e.g. tamsulosin), hair loss (usually from the body) or hair growth, changes in your mood, feeling depressed, breast swelling or tenderness and testicular pain or swelling.

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.

APO-DUTASTERIDE

Active ingredient: *dutasteride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-DUTASTERIDE. **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 APO-DUTASTERIDE.**

Where to find information in this leaflet:

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

1. Why am I using APO-DUTASTERIDE?

APO-DUTASTERIDE contains the active ingredient dutasteride. APO-DUTASTERIDE belongs to a group of medicines called 5 alpha reductase enzyme inhibitors.

APO-DUTASTERIDE is used to in men who have 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 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). APO-Dutasteride lowers DHT production in the body, leading to a shrinkage of the enlarged prostate in most men.

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

APO-DUTASTERIDE may also be taken in combination with another type of medicine called an alpha blocker (e.g. tamsulosin) in order to treat symptoms of an enlarged prostate.

2. What should I know before I use APO-DUTASTERIDE?

Warnings

Do not use APO-DUTASTERIDE if:

- you are allergic to dutasteride, 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 severe liver disease

Check with your doctor if you:

- have any other medical conditions
- 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 APO-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.

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 APO-DUTASTERIDE and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-DUTASTERIDE.

4. How do I use APO-DUTASTERIDE?

How much to take

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

When to take APO-DUTASTERIDE

- APO-DUTASTERIDE can be taken with or without food.

How to take APO-DUTASTERIDE

- Swallow the capsule whole with some water.
- Do not crush, chew or open the capsules. The contents of the capsule may make your mouth or throat sore.

If you forget to use APO-DUTASTERIDE

APO-DUTASTERIDE should be used regularly at the same time each day.

If it is almost time for your next dose, 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 APO-DUTASTERIDE

If you think that you have used too much APO-DUTASTERIDE, 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 APO-DUTASTERIDE?

Things you should do

Tell your doctor straight away if you:

- have not taken APO-DUTASTERIDE exactly as directed
- are having blood test, tell your doctor you are taking APO-DUTASTERIDE 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 level of PSA in your blood it could mean that you have a higher risk of prostate cancer. Men taking APO-DUSTASTERIDE 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 APO-DUTASTERIDE.

Things to be careful of

APO-DUTASTERIDE may be taken in combination with another type of medicine called an alpha blocker (e.g. tamsulosin) in order to treat symptoms of an enlarged prostate. If you are going to have a surgery, tell your surgeon that you are taking or have taken an alpha blocker.
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 than in men who did not take dutasteride. The reasons for this are currently unknown but may be due to the design of the clinical study.

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 APO-DUTASTERIDE 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 APO-DUTASTERIDE and 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 condition.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-DUTASTERIDE affects you.

Looking after your medicine

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

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

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 APO-DUTASTERIDE in the original pack until it is time to take your dose.

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.

If you are taking APO-DUTASTERIDE and an alpha-blocker, talk to your doctor about 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
• impotence (inability to achieve or maintain an erection) • decrease in libido (sex drive) • difficulty with ejaculation • decrease in sperm count and semen volume • dizziness when taken with an alpha blocker (e.g. tamsulosin) • hair loss (usually from the body) or hair growth • changes in your mood, feeling depressed	**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 – signs include wheezing, difficulty breathing, swelling of face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin and fainting • 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 they could be signs of a serious condition such as breast cancer • testicular pain and/or swelling	**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.**

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 APO-DUTASTERIDE contains

Active ingredient (main ingredient)	**Dutasteride**
Other ingredients (inactive ingredients)	• Glyceryl caprylate/caprate • butylated hydroxytoluene • gelatin • glycerol • water – purified • iron oxide yellow CI77499 • titanium dioxide • Sulfites • OPACODE monogramming ink S-1-15095 Red (PI#12470).
Potential allergens	Contains sulfites May contain trace amounts of phenylalanine.

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

What APO-DUTASTERIDE looks like

APO-DUTASTERIDE is an oily, colourless to pale yellow liquid absent of any visible particles and/or crystals in a pale yellow, oblong gelatin capsule printed with 'A 0.5' on one side in red ink. (Aust R 212047).

Who distributes APO-DUTASTERIDE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121
Australia
www.arrotex.com.au

This leaflet was prepared in September 2024.