

TEROD®

Dutasteride

500 micrograms soft gelatin capsules

What is in this leaflet

Please read this leaflet carefully before you start taking TEROD.

This leaflet answers some common questions about TEROD. It does not contain all 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 risks of you taking TEROD against the benefits they expect it will 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 TEROD is used for

The active ingredient in TEROD capsules, dutasteride, belongs to a group of medicines called 5-alpha reductase enzyme inhibitors, which is used in men who have a medical condition known as benign prostatic hyperplasia (BPH).

BPH, a non-cancerous enlargement of the prostate gland is located at the lower portion of the urinary bladder surrounding the urethra (urine carrying tube). In men with BPH, the prostate gland develops 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 beginning to urinate
- more frequent urination, especially at night

- feeling the need to urinate right away
- an interrupted, weak urinary flow
- leaking or dribbling
- a feeling that you cannot empty your bladder completely.

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

Prostate growth is caused by dihydrotestosterone (DHT), which is a hormone in the blood.

TEROD decreases DHT production in the body. This leads to shrinkage of the enlarged prostate in most men. Your prostate grows large over a long amount of time; therefore, decreasing your prostate size and improving your symptoms may also take time.

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

Ask your doctor if you have any questions about why TEROD has been prescribed for you.

Your doctor may have prescribed TEROD for another reason.

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

TEROD is not addictive.

Before you take TEROD

When you must not take it

Do not take TEROD if you have an allergy to:

- any medicine containing dutasteride or a class of medicines called 5-alpha reductase enzyme inhibitors
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take TAROD if you are a woman or a child.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tempering.

If you are not sure whether you should start taking TEROD, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you suffer from liver disease and/or other medical conditions.

Avoid touching any punctured or leaking capsules. Women, who are pregnant or may be pregnant, and children must avoid touching any punctured or leaking capsules. If there is any contact with the skin, wash the affected area with soap and water immediately. If dutasteride is absorbed through the skin by a pregnant woman with a male baby, it may cause the male baby to be born with genital organ abnormalities.

Use a condom during sexual intercourse.

Dutasteride has been detected in the semen of men taking TEROD capsules. So, 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. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.

If you have not told your doctor about any of the above, tell them before you start taking TEROD.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking TEROD.

Some medicines can react with TEROD and may make it more likely that you will have side-effects. These medicines include:

- alpha-blockers (for enlarged prostate or high blood pressure).
- verapamil or diltiazem (medicines used for high blood pressure)

How to take TEROD

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

The recommended dose is one capsule (500 micrograms) taken once a day.

How to take it

Swallow the capsules whole with water. Do not chew or break open the capsule. Contact with the contents of the capsules may make your mouth or throat sore.

When to take it

Take TEROD with or without food at about the same time each day.

Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

How long to take it

It is vital to keep taking TEROD for as long as your doctor has prescribed it, even if you do not feel any immediate benefit. While some men notice an early improvement in their symptoms, others may need to continue taking it for 3-6 months to see if TEROD helps them. You must also carry on taking your medicine as your symptoms improve.

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

If you forget to take it

Do not take a double dose to make up for the one you have missed. If you forget to take a capsule, do not worry, just take the next dose as normal and continue as before.

If you are not sure what to do, or for any reason, you have not taken your medicine exactly as directed, ask your doctor or pharmacist.

While you are taking TEROD

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking TEROD.

Use a condom during sexual intercourse.

Dutasteride has been detected in the semen of men taking TEROD capsules. So, 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.

Keep all of your doctor's appointments so that your progress can be checked.

Men taking TEROD should have their PSA (Prostate-specific antigen) levels measured 6 months after beginning treatment and then have their PSA levels measured regularly after that.

Things you must not do

Do not give TEROD to anyone else, even if they have the same condition as you.

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

Do not donate blood while taking TEROD until 6 months after stopping treatment.

Things to be careful of

Be careful driving or operating machinery until you know how you react to TEROD. Usually, TEROD does not cause any problems with your ability to drive a car or operate machinery.

If you are taking TEROD and an alpha-blocker, speak with your doctor about heart failure and other possible side effects. In clinical studies involving dutasteride, patients taking dutasteride and an alpha-blocker (for example tamsulosin) had heart failure more often than patients taking only dutasteride or only an alpha blocker. Heart failure means your heart does not pump blood as well as it should.

In a clinical study of men with an 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 event is currently unknown but may be related to the design of the clinical study.

The amount of PSA, a substance in your blood can be measured through a blood test and this 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, this could mean that you are at a higher risk of prostate cancer.

Taking TEROD will decrease 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 find prostate cancer, by comparing your test results each time you have a PSA test.

It is crucial to take your medicine as your doctor has told you to. If you do not take your medicine regularly, it may interfere with your doctor's ability to monitor your PSA.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much TEROD.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TEROD.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

The most commonly reported side effects are:

- inability to achieve or maintain an erection (impotence)
- decrease in libido (sex drive)
- trouble with ejaculation
- swelling or tenderness of breasts
- dizziness when taken in combination with an alpha blocker.

Rarely, the following side effects have been reported:

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

Very rarely, the following side effects have been reported:

- depressed mood
- testicular pain and testicular swelling

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

If any of the following happen, stop taking TEROD and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Hives
- Fainting

These are very serious side effects. If you have them, you may have had a serious allergic reaction to TEROD. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

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

After taking TEROD

Storage

Keep your capsules in its blister pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature stays at or below 30°C.

Do not store TEROD in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it 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

Return any unused medicine to your pharmacist. If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

TEROD capsules are light brown, oblong, soft gelatin capsules.

Ingredients

Active ingredient(s):

Dutasteride 500 micrograms

Inactive ingredients:

Butylated hydroxytoluene, gelatin, glycerol iron oxide red, iron oxide yellow, octanoic/decanoic acid glycerides, and titanium dioxide

Sponsor details

TEROD is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

20 October 2017

(based on data sheet dated 20 October 2017)