

inTASTERIDE Soft Gelatin Capsules

Dutasteride 0.5mg

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What inTASTERIDE is used for

inTASTERIDE is used to treat men with an enlarged prostate (benign prostatic hyperplasia) - a non-cancerous growth of the prostate gland caused by producing too much of a hormone called DHT (dihydrotestosterone).

How inTASTERIDE works

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors. As the prostate grows, it can lead to urinary problems, such as difficulty in passing urine and the need to go to the toilet more frequently. It can also cause the flow of the urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked. InTASTERIDE helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces.

Before you use inTASTERIDE

When you must not use it

You must not use inTASTERIDE if you:

- are allergic to dutasteride or any of the other ingredients

of inTASTERIDE, or to similar medicines known as 5-alpha reductase inhibitors.

- if you are female, children and adolescents. This medicine is for adult men only.
- if you have severe liver impairment

If any of these apply to you, do not take inTASTERIDE until you have checked with your doctor.

Women who are pregnant (or may be) must not handle leaking capsules. Dutasteride is absorbed through the skin and can affect the normal development of a male baby.

Contact your doctor for advice if a pregnant woman has come into contact with the contents of inTASTERIDE.

Before you start to use it

If you have liver disease, check with your doctor if inTASTERIDE is suitable for you. You may need extra check-ups while you are taking inTASTERIDE

Taking other medicines

Patients taking inTASTERIDE and an alpha-blocker had heart failure more often than patients taking only inTASTERIDE or only an alpha-blocker. Heart failure means your heart does not pump blood as well as it should.

If you are taking inTASTERIDE and an alpha-blocker, talk to your doctor about this and other possible side effects.

Tell your doctor if you are taking any other medicines, or have recently taken any. This includes medicines bought without a prescription.

How to use inTASTERIDE

How much to use

Always take inTASTERIDE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one capsule (0.5 mg) taken once a day.

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

When to use it

Always take inTASTERIDE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How long to use it

Take inTASTERIDE for as long as your doctor recommends. Do not stop taking inTASTERIDE without talking to your doctor first.

inTASTERIDE is a long-term treatment. Some men notice an early improvement in their symptoms. However, others may need to continue treatment for up to 6 months to see if inTASTERIDE helps them.

If you forget to use it

Do not take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

If you use too much (overdose)

If you take too many inTASTERIDE capsules, contact your doctor or pharmacist for advice. If possible, show them the inTASTERIDE pack.

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While You Are Using It

Things you must do

Men at increased risk of prostate cancer, men taking Dutasteride had a serious form of prostate cancer more often than men who did not take Dutasteride.

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 inTASTERIDE should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking inTASTERIDE 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.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Blood Donation: Men being treated with dutasteride should not

donate blood until at least 6 months have passed following their last dose. The purpose of this deferred period is to prevent administration of dutasteride to a pregnant female transfusion recipient

Things to be careful of

inTASTERIDE has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by inTASTERIDE.

Women, children and adolescents must not handle leaking inTASTERIDE capsules, because the active ingredient can be absorbed through the skin. Wash the affected area immediately with soap and water if there is any contact with the skin.

inTASTERIDE may cause breast enlargement and 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.

Dutasteride would not be expected to interfere with the ability to drive or operate machinery.

Side Effects

Like all medicines, inTASTERIDE can cause side effects, but not everybody gets them:

Conditions you need to look out for

Allergic reaction. Signs can include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
- collapse

Contact a doctor immediately if you get any of these symptoms. Stop taking inTASTERIDE.

Common side effects

- not able to achieve or maintain an erection (impotence)*
- decreased sex drive
- difficulty with ejaculation*
- breast enlargement or tenderness
- dizziness when taken with tamsulosin.

*In a small number of people some of these events may continue after they stop taking inTASTERIDE

Rare side effects

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

Very rare side effects

- depressed mood
- pain and swelling in your testicles

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of inTASTERIDE

Storage

Keep inTASTERIDE out of reach of children.

Do not store above 30°C. Keep blister in the outer cardboard carton in order to protect from light

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Disposal

Do not use after the expiry date stated on the label. Do not throw them away with your normal household water or waste. This will help to protect the environment.

58000 Kuala Lumpur
Wilayah Persekutuan Kuala Lumpur

Date of revision

21/04/2026

Product Description

What it looks like

inTASTERIDE 0.5 mg Soft Gelatin Capsules: oblong soft gelatin capsules (approximately 16.5 x 6.5 mm) of light-yellow colour, filled with transparent liquid

Serial Number

NPRA(R2/2)260415/00043

Ingredients

Active Ingredient

Dutasteride 0.5mg

Inactive Ingredients:

Capsule contents:

Propylene Glycol

Monocaprylate

Butylhydroxytoluene

Capsule shell:

Bovine Gelatin

Glycerol

Titanium dioxide (E171)

Triglycerides (medium chain)

Lecithin (may contain soya oil)

MAL Number(s)

inTASTERIDE 0.5 mg Soft Gelatin Capsules:

MAL23076014AZ

Manufacturer

Laboratorios León Farma, S.A
C/ La Vallina s/n, Polígono Industrial Navatejera,
Villaquilambre, 24193 León
(Spain)

Product Registration Holder

Intega Sdn. Bhd.
8-08, Level 8, Menara MBMR,
No. 1, Jalan Syed Putra,