# BUDIDA SOFT CAPSULES

Dutasteride (0.5mg)

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**What Budida is used for**

Budida 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 Budida 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 a 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.

Budida helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces.

**Before you use BUDIDA**

- *When you must not use it*

- if you are allergic (hypersensitive) to dutasteride or to any of the other ingredients of Budida, or to other 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 Budida 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 Budida capsule.

- *Before you start to use it*

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

- *Taking other medicines*

The patients taking Budida and an alpha-blocker (example tamsulosin) had heart failure more often than patients taking only Budida or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.)

If you are taking Budida and 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 BUDIDA**

- *How much to use*

Always take Budida 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 (0.5mg) taken once a day.

- *How to take*

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

- *When to use it*

Always take Budida 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 Budida for as long as your doctor recommends. Do not stop taking Budida without talking to your doctor first.

Budida 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 Budida 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 Budida capsules, contact your doctor or pharmacist for advice. If possible, show them the Budida pack.

**While you are using it**

- *Things you must do*

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.

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Men taking Budida should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking Budida 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*

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

Women, children and adolescents must not handle leaking Budida 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.

Budida 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 ofa 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, Budida 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 Budida.

*Common side effects*

- not able to achieve or maintainan erection (impotence)*
- decreased sex drive
- difficulty with ejaculation*
- breast enlargement ortenderness
- dizziness when taken withtamsulosin.

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

*Rare side effects*

- hair loss (usually from thebody) 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 of 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 Medicine (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Budida**

- *Storage*

Keep out of the reach and sight of children.
Do not use Budida after the expiry date shown on the pack.
Do not store Budida above 30ºC.

- *Disposal*

If you have any unwanted Budida capsules, do not dispose of them in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

**Product Description**

- *What is looks like*

Budida is an opaque, light yellow, and oblong soft capsule, contains homogenous and clear liquid.

- *Ingredients*

*Active ingredient(s)*

Each capsule contains 0.5mg dutasteride.

*Inactive ingredient(s)*

Capsule content:
Monodiglycerides of caprylic / capric acid, Butylated hydroxytoluene

Capsule shell:
Gelatin (softgels), Glycerin (Concentrated Glycerin), Titanium dioxide, Yellow ferric oxide, Light liquid paraffin, Purified water

- *MAL number*

MALXXXXXXXX

# BUDIDA SOFT CAPSULES

Dutasteride (0.5mg)

**Manufacturer**

Pei Li Pharmaceutical Industrial Co., Ltd
No. 11, Gongyequ 6th Rd, Xitun Dist.,
Taichung City, 40755,
TAIWAN (R.O.C).

**Product Registration Holder**

GK Bio International Sdn. Bhd.
No. 42-2, Jalan PJU 5/11,
Kota Damansara, 47810 Petaling Jaya,
Selangor.

**Date of Revision**

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