

# BICALOX FILM COATED TABLET 50MG

(Bicalutamide)

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## What BICALOX is used for

BICALOX 50mg is used to treat locally advanced prostate cancer

## How BICALOX works

**BICALOX** is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens can help the cancer cells to grow. BICATULAMIDE interferes with some of the actions of these hormones.

**BICALOX** is only be taken by men. You must follow all the directions given to you by your doctor.

They can differ from the information in this leaflet.

Your doctor can prescribe this medicine for another use. Always ask your doctor if you need more information.

**BICALOX** is not known to be additive..

## Before you use BICALOX

### - When you must not use it

Do not take **BICALOX** if you are a woman. Women do not get treated with **BICALOX**.

Do not give **BICALOX** to children. There is no experience of treating children with **BICALOX**

Do not take **BICALOX** if you are allergic to bicalutamide or any of the other ingredients in **BICALOX**.

Do not take **BICALOX** after the use by (expiry) date printed on the pack. It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take **BICALOX** if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

### - Before you start use it

You must tell your doctor if:

1. You have allergies to:
  - Bicalutamide, the active ingredient in **BICALOX**
  - Any of the other ingredients of **BICALOX** 50mg listed at the end of this leaflet
  - Other anti-androgen medicines
  - Any other medicines
  - Any other substances, such as foods, preservatives or dyes
2. You have liver problems

If you have problems with your liver, it may not be safe for you to take **BICALOX**.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines that you buy without a prescription and herbal medicines.

Do not take **BICALOX** if you are already taking any of the following medicines:

- Cisapride (used for some types of indigestion)
- Certain anti-histamine medicines (terfenadine or astemizole)

Also, tell your doctor if you are taking any of the following medicines:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants i.e warfarin)
- Ciclosporin (to suppress your immune system)
- Calcium channel blockers (to treat high blood pressure or some heart conditions)
- Cimetidine and ketoconazole

## How to use BICALOX

### - How much to use

The usual adult dose is one 50mg tablet taken each day.

Swallow your **BICALOX** tablet whole with a full glass of water.

### - When to use it

Take **BICALOX** before food, at about **BICALOX** Film Coated Tablet 50mg 2 the same time each day.

### - How long to use it

Continue taking **BICALOX** for as long as your doctor or pharmacist tells you.

### - If you forget to use it

If you miss a dose take it as soon as you remember, as long as it is 12 hours before the next dose is due. If it is less than 12 hours to the next dose do not take the dose you have missed.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have troubled remembering to take your medicine, ask your pharmacist for some hints.

### - If you use too much (overdose)

Immediately call your doctor or pharmacist or go to nearest hospital, if you think that you or anyone else may have taken too much **BICALOX**. Do this even if there are no signs of discomfort or poisoning.

## While you are using it BICALOX

### - Things you must do

Be sure to keep all your appointments with your doctor so your progress can be seen.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking **BICALOX**.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking **BICALOX**.

If you go to hospital, please let the medical staff know that you are taking **BICALOX**.

### - Things you must not do

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

Do not take **BICALOX** to treat any other complaints unless your doctor tells you to.

Do not stop taking **BICALOX**, or lower the dosage, without checking with your doctor.

### - Things to be careful of

Be careful driving or operating machinery until you know how **BICALOX** affects you.

Some patients may feel dizzy or weak.

## Side effects

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

**BICALOX** helps people with locally advanced prostate cancer, but it may have unwanted side effects.

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 side effects.

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

Tell your doctor as soon as possible if you notice any of the following and they

worry you.

## Allergic reactions:

These are uncommon. The symptoms can include sudden onset of:

- Rash, hives or severe itching of the skin
- Swelling of the face, lips, tongue, throat or other parts of the body which may cause difficulty in swallowing
- Shortness of breath

If this happens to you, see a doctor straight away.

Very common:

- Pain in your abdomen
- Blood in your urine.

Common

- Yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or in rare cases liver failure.

Uncommon:

- Serious shortness of breath or shortness of breath which suddenly gets worse. This may be with a cough or high temperature (fever). These may be signs of an inflammation of the lungs called 'interstitial lung disease'.

Other possible side effects:

## Very common

- Dizziness
- Hot flushes
- Constipation
- Feeling sick (nausea)
- Breast tenderness or changes in breast size
- Feeling weak
- Swelling
- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.

## Common

- Loss of appetite
- Reduced sex drive
- Depression
- Feeling sleepy
- Heart attack
- Reduced heart function
- Indigestion

- Wind (flatulence)
- Hair loss
- Hair re-growth or growth of extra hair
- Dry skin
- Itching
- Skin rash
- Being unable to get an erection (impotence)
- Chest pain
- Weight gain

Occasionally **BICALOX** may be associated with changes in your blood, which may require your doctor to do certain blood tests. These are possible side effects of **BICALOX**.

Some people may get other effects while taking **BICALOX**.

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.moh.gov.my](http://npra.moh.gov.my) [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)].

## Storage and Disposal of BICALOX

### - Storage

Keep your **BICALOX** tablets in the blister foil until it is time to take them. If you take **BICALOX** out of the blister foil, it will not keep well.

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days. Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

### - Disposal

Ask your pharmacist what to do with any

tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help protect the environment.

### **Product Description**

#### **- What it looks like**

**BICALOX** Film coated tablet 50mg is a white to off-white, round, film-coated, binconvex tablets, engraved with 'BC 50' on one face and plain on the other.

**BICALOX Film** coated tablet 50mg are packed in blister foils of 28 tablets.

#### **- Ingredients**

The active substance is bicalutamide 50mg.

Inactive ingredients: Lactose, sodium starch glycolate, povidone, magnesium stearate, opadry white.

#### **- MAL number:**

MAL15065029ACZ

### **Manufacturer**

**Douglas Manufacturing Ltd**

Central Park Drive

Lincoln, AUCKLAND

### **Product Registration Holder**

**SCHMIDT BioMedTech Sdn Bhd**

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### **Date of revision**

16/08/2023

### **Serial Number**

NPRA(R2/1)220203/831