

Table of Contents

1.3.2.1 PIL - Approved.....	1
<i>1 What BICALUTAMIDE AURO is and what it is used for.....</i>	<i>2</i>
<i>2. What you need to know before you take BICALUTAMIDE AURO</i>	<i>2</i>
<i>3. How to take BICALUTAMIDE AURO</i>	<i>4</i>
<i>4. Possible side effects</i>	<i>5</i>
<i>5. How to store BICALUTAMIDE AURO.....</i>	<i>8</i>
<i>6. Contents of the pack and other information.....</i>	<i>9</i>

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO
Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

APPROVED Patient Information Leaflet

PATIENT INFORMATION LEAFLET

S4

SCHEDULING STATUS

BICALUTAMIDE 50 mg AURO film-coated tablet

BICALUTAMIDE 150 mg AURO film-coated tablet

Bicalutamide

Contains sugar: Lactose 61 mg or 183 mg respectively per tablet.

Read all of this leaflet carefully before you start taking BICALUTAMIDE AURO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BICALUTAMIDE AURO** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **BICALUTAMIDE AURO** is and what it is used for
2. What you need to know before you take **BICALUTAMIDE AURO**
3. How to take **BICALUTAMIDE AURO**
4. Possible side effects
5. How to store **BICALUTAMIDE AURO**
6. Contents of the pack and other information

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

1 What BICALUTAMIDE AURO is and what it is used for

Bicalutamide belongs to a group of medicines called non-steroidal anti-androgen.

Bicalutamide works by interfering with the actions of male sex hormones (androgens).

BICALUTAMIDE 50 MG AURO is used for the treatment of advanced prostate cancer in combination with hormone therapy or after surgery.

BICALUTAMIDE 150 MG AURO is used for the treatment of prostate cancer that has not spread to other parts of the body for which other treatment including surgery is not appropriate.

2. What you need to know before you take BICALUTAMIDE AURO

Do not take BICALUTAMIDE AURO:

- if you are hypersensitive (allergic) to bicalutamide or any of the other ingredients of **BICALUTAMIDE AURO** (listed in section 6)
- If you are a female, child, pregnant woman or breastfeeding mother.
- If you are taking medicines containing terfenadine (to treat allergies), astemizole (allergies) or cisapride (to treat stomach disorders)

Warnings and precautions

Special care should be taken with **BICALUTAMIDE AURO**:

- if you have moderate to severe liver impairment your doctor will monitor your liver function during treatment with **BICALUTAMIDE AURO**
- if you have non-alcoholic fatty liver disease (NAFLD) and associated liver disease
- if you are hospitalised warn the doctor that you are taking **BICALUTAMIDE AURO**
- if you have any of the following: Any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

The risk of heart rhythm problems may be increased when using **BICALUTAMIDE AURO**

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

- if you have diabetes and are already taking an medicines known as 'LHRH analogues'.
These include goserelin, buserelin, leuprorelin and triptorelin. The active substance in this medicine (bicalutamide) can have a negative effect on the level of sugar in your blood.
Your doctor will therefore want to check your blood sugar levels regularly
- if you are taking **BICALUTAMIDE AURO**, you and/or your partner should use birth control while you are taking **BICALUTAMIDE AURO** and for 130 days after stopping **BICALUTAMIDE AURO**. Talk to your doctor or pharmacist if you have any questions about birth control.
- if you are taking blood thinners or medicines to prevent blood clots

Other medicines and BICALUTAMIDE AURO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking the following medicines:

- Ketoconazole (medicine used to treat fungal infections)
- Cimetidine (medicine for ulcers or heartburn)
- Anti-coagulants e.g. warfarin (medicines that prevent the blood from clotting).
- Calcium channel blockers (to treat high blood pressure or some heart condition)
- Ciclosporin (to suppress your immune system)
- Midazolam (sleeping tablets), terfenadine (to treat allergies), astemizole (allergies) or cisapride (to treat stomach disorders)

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO
Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **BICALUTAMIDE AURO**.

You should not take **BICALUTAMIDE AURO** if you are pregnant or breastfeeding

Driving and using machines

BICALUTAMIDE AURO has no effect on the ability to drive or operate machinery.

BICALUTAMIDE AURO contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **BICALUTAMIDE AURO**.

BICALUTAMIDE AURO contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take BICALUTAMIDE AURO

Do not share medicines prescribed for you with any other person. Always take **BICALUTAMIDE AURO** exactly as your doctor has instructed you. Your doctor will tell you how long your treatment with **BICALUTAMIDE AURO** will last. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BICALUTAMIDE AURO** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is one tablet each day.

Take your medication exactly as directed by your doctor.

Swallow your tablet whole with a drink of water.

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO
Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

Take this medicine at the same time each day to avoid missing any doses.

Do not stop taking **BICALUTAMIDE AURO** without speaking with your doctor first.

BICALUTAMIDE AURO can cause changes to certain blood tests that your doctor may want to check.

Before having any kind of surgery, including dental or emergency treatment, tell your surgeon, dentist or doctor that you are taking **BICALUTAMIDE AURO**

If you take more BICALUTAMIDE AURO than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take BICALUTAMIDE AURO

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

4. Possible side effects

BICALUTAMIDE AURO can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while **BICALUTAMIDE AURO**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **BICALUTAMIDE AURO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

- infection (cough or hoarseness, fever, runny nose),
- unusual tiredness or weakness,
- shortness of breath or difficulty breathing,
- swelling of face, lips, tongue and and/or throat, which may cause difficulty in swallowing, severe itching of the skin (with raised lumps)
- fever,
- bloody or black, tarry stools,
- blood in your urine,
- dark urine, 'flu-like' symptoms, gastrointestinal upset, yellow eyes, or skin,
- symptoms of non-alcoholic fatty liver disease like fatigue, pain, or weight loss, and over time inflammation of the liver.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- constipation, diarrhoea, nausea, weakness,
- abdominal pain, bloated feeling, flatulence, or indigestion,
- chills, confusion, decrease or loss of appetite, dizziness, drowsiness,
- breast tenderness or swelling.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- low sex drive

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

- depression
- tight chest
- hot flushes
- hair loss
- hair re-growth
- itchy skin
- weight gain
- erectile dysfunction
- rash

Less frequent side effects

- raised blood pressure,
- sore throat,
- muscle pains, weakness and difficulty moving
- numbness tingling, burning of hands/feet
- gastrointestinal or rectal bleeding (passing blood in stools),
- vomiting,
- sensitivity to light,
- headache,
- abdominal discomfort (bloating, gas)
- liver problems
- confusion
- dry mouth
- nervousness
- runny nose
- drowsiness

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

- chills

The following may also occur:

- low body weight
- waking up more than once during the night because you have to pee
- raised glucose levels,
- chest pain (arising from the heart),
- irregular heartbeat,
- sweating

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **BICALUTAMIDE AURO**.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. "By reporting side effects, you can help provide more information on the safety of **BICALUTAMIDE AURO**."

5. How to store BICALUTAMIDE AURO

Do not store your medicine above 25 °C.

Store in the original container.

Do not use this medicine after the expiry date shown on the carton.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BICALUTAMIDE AURO contains:

The active substance is bicalutamide.

The other ingredients are:

lactose monohydrate Ph. Eur

sodium starch Glycolate (Type A) Ph. Eur. 7

povidone Ph.Eur

purified water Ph.Eur

magnesium stearate Ph.Eur

Opadry® complete film coating system

02B58900 white IH (HPMC 2910/HYPROMELLOSE, TITANIUM DIOXIDE, MACROGOL/PEG)

What BICALUTAMIDE AURO looks like and contents of the pack

BICALUTAMIDE 50 MG AURO Round, white film coated tablets debossed with “B” on one side and “I” on the other side.

BICALUTAMIDE 150 MG AURO White, biconvex, round, film-coated tablet, debossed with ‘E150’ on one side and plain on the other side.

Proprietary name: BICALUTAMIDE 50 mg AURO and BICALUTAMIDE 150 mg AURO

Each film coated tablet contains Bicalutamide 50 mg or 150 mg respectively

BICALUTAMIDE AURO is packaged in:

Blister Pack

Clear 250 micron PVC film - aluminium foil blister pack:

Blister pack comprises of Clear 250 micron PVC film as the forming material and 25 micron aluminium foil as the lidding material.

Clear 250 micron PVC/PVDC film - aluminium foil blister pack:

Blister pack comprises of Clear 250 micron PVC film as the forming material and 25 micron aluminium foil as the lidding material.

Package leaflets will be packed into preprinted cartons

Pack size: 10s

Holder of Certificate of Registration

Aurogen South Africa (Pty) Ltd.

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue,

Meyersdal, Ext. 12,

1448, Johannesburg,

South Africa.

This leaflet was last revised in

21 July 2026

Registration number (s):

BICALUTAMIDE 50 MG AURO: 59/21.12/0748

BICALUTAMIDE 150 MG AURO: 59/21.12/0749