

FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Bicalutamide 150 Accord (150 mg, film coated tablet)

Bicalutamide

Contains sugar (lactose monohydrate).

Read all of this leaflet carefully before you are given Bicalutamide 150 Accord

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Bicalutamide 150 Accord 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 150 Accord is and what it is used for
2. What you need to know before you use Bicalutamide 150 Accord
3. How to use Bicalutamide 150 Accord
4. Possible side effects
5. How to store Bicalutamide 150 Accord
6. Contents of the pack and other information

1. What Bicalutamide 150 Accord is and what it is used for

Bicalutamide 150 Accord 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 use Bicalutamide 150 Accord

Bicalutamide 150 Accord should not be administered to you:

- if you are hypersensitive (allergic) to Bicalutamide 150 Accord or any of the other ingredients of Bicalutamide 150 Accord (listed in section 6).
- In women and children
- If you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole)

Do not take Bicalutamide 150 Accord if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Bicalutamide 150 Accord.

Warnings and Precautions

Take special care with Bicalutamide 150 Accord in the following instances:

Before taking Bicalutamide 150 Accord tell your doctor, pharmacist or other healthcare professional:

- If you are suffering from any disorder or disease which affects your liver.
- If you are taking any other medicines including those which you have bought. In particular if you are taking oral anti-coagulants (to prevent blood clots).

While you are taking Bicalutamide 150 Accord tell your doctor, pharmacist or other healthcare professional:

- If you experience any problems that could be due to your liver, such as becoming jaundiced (yellowing of the skin and eyes) etc.

Taking Bicalutamide 150 Accord with food and drink:

Do not take Bicalutamide 150 Accord with grapefruit juice as this may affect how Bicalutamide

SAHPRA CLINICAL TEMPLATE 07/2020
Applicant/HCR: Accord Healthcare (Pty) Ltd
Bicalutamide 150 Accord (Film coated tablet)
Strength: 150 mg

150 Accord works.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, you should not take Bicalutamide 150 Accord.

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 this medicine.

Pregnancy and breastfeeding:

- Bicalutamide 150 Accord should not be given to women.

Driving and using machinery:

Do not drive because Bicalutamide 150 Accord could interfere with your ability to drive or use machines.

It is not always possible to predict to what extent Bicalutamide 150 Accord may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Bicalutamide 150 Accord affects them.

Important information about some of the ingredients of Bicalutamide 150 Accord:

Lactose Warning:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Bicalutamide 150 Accord.

Other medicines and Bicalutamide 150 Accord

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

Please consult your doctor, pharmacist or other healthcare professional for advice.

This is because Bicalutamide 150 Accord may affect the way some other medicines work. Also, some other medicines may affect the way Bicalutamide 150 Accord works.

If you are taking any of the following medicines tell your doctor, pharmacist or other health care professional:

- Midazolam and ciclosporin
- Warfarin

3. How to use Bicalutamide 150 Accord

Do not share medicines prescribed for you with any other person.

Follow your doctor, pharmacist, or other health care professional's instructions on how to take Bicalutamide 150 Accord and ask them if you are unsure.

- If you feel that the effect of Bicalutamide 150 Accord is too strong or too weak, tell your doctor or pharmacist

If you have the impression that the effect of Bicalutamide 150 Accord is too strong or too weak, tell your doctor or pharmacist.

The usual dose:

Adults: Take one tablet once a day.

If you receive more Bicalutamide 150 Accord than you should:

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

If you forget to take Bicalutamide 150 Accord

If you forget to take a dose, then take the dose as soon as possible or take the next dose as usual.

Do not take 2 doses at the same time

4. Possible side effects

Bicalutamide 150 Accord can have side effects.

Not all side effects for Bicalutamide 150 Accord are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Bicalutamide 150 Accord, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens:

- severe itching of the skin (with raised lumps) or swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- yellow skin and eyes (jaundice). These may be symptoms of liver damage.
- blood in urine
- abdominal pain

Side effects that may occur frequently:

- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. Some patients taking Bicalutamide 150 Accord get an inflammation of the lungs called interstitial lung disease.

Tell your doctor as soon as possible if any of the following side effects bother you:

The following side effects may occur frequently:

SAHPRA CLINICAL TEMPLATE 07/2020
Applicant/HCR: Accord Healthcare (Pty) Ltd
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Strength: 150 mg

- tender or enlarged breast tissue
- hot flushes
- nausea
- itching
- feeling weak
- dizziness
- rash
- dry skin
- chest pain
- loss of appetite
- reduced sex drive
- impotence
- depression
- sleepiness
- indigestion
- flatulence
- loss of hair or hair re-growth
- weight gain
- puffiness/swelling
- reduced heart function, or heart attack

Bicalutamide 150 Accord may also be associated with changes in your blood which may require your doctor to do certain blood tests. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04**

Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Bicalutamide 150 Accord.

5. How to store Bicalutamide 150 Accord

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Store in original package until use.
- Do not use after the expiry date stated on the label.
- 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 150 Accord contains

- The active substance is bicalutamide
- Each tablet contains 150 mg bicalutamide
- The other ingredients are Lactose monohydrate, Sodium starch glycolate, Povidone K-30, Sodium starch glycolate, Magnesium stearate which make up the tablet core and Hypromellose, Titanium dioxide, Macrogol 400 which make up the film-coat.

What Bicalutamide 150 Accord looks like and contents of the pack

- Film-coated tablets
- White to off white, round, biconvex, film coated tablets debossed 'I01' on one side and plain on other side.
- Clear PVC/PVdC-Aluminium blister pack comprising strips of 5, 10, and 14 tablets to give

SAHPRA CLINICAL TEMPLATE 07/2020
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pack sizes of 10, 20, 30, 40, 50, 80, 90, 100, 200 or 14, 28, 56, 84, 140 and 280 tablets.

HOLDER OF CERTIFICATE OF REGISTRATION

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