



addiction detoxification), moxifloxacin (an antibiotic)], antipsychotics used for serious mental illnesses.

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

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants) e.g. warfarin. Blood thinners or medicines to prevent blood clots.
- Ciclosporin (to suppress your immune system).
- Calcium channel blockers (to treat high blood pressure or some heart conditions).
- Cimetidine (for stomach problems).
- Ketoconazole (to treat infections caused by a fungus).

Pregnancy, breast-feeding and fertility

Bicalutamide must not be taken by women, including pregnant women or mothers who are breast-feeding their babies.

Bicalutamide may have an effect on male fertility which could be reversible.

Driving and using machines

Bicalutamide is not likely to affect you being able to drive or use any tools or machines.

However, if you feel sleepy take care with these activities.

Bicalutamide contains lactose

Bicalutamide contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE BICALUTAMIDE TABLETS 50MG

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose for an adult is one tablet each day.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.
- Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

If you take more Bicalutamide than you should

If you take more Bicalutamide than prescribed by your doctor, talk to a doctor or go to a hospital straight away.

If you forget to take Bicalutamide



- If you forget to take a dose, skip the missed dose and take the next dose as usual.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

These are uncommon (may affect up to 1 in 100 people):

The symptoms can include sudden onset of:

- Rash, itching or hives on the skin.
- Swelling of the face, lips, tongue, throat or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

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

Also tell your doctor straight away if you notice any of the following:

Very common (may affect more than 1 in 10 people):

- Pain in your abdomen.
- Blood in your urine.

Common (may affect up to 1 in 10 people):

- Yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or in rare cases (may affect up to 1 in 1,000 people) liver failure.

Uncommon (may affect up to 1 in 100 people):

- 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'.

Not known (frequency cannot be estimated from the available data):

- Changes in ECG (QT prolongation).

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Dizziness.
- Constipation.
- Feeling sick (nausea).



- Swelling and tenderness of your breasts.
- Hot flushes.
- Feeling weak.
- Swelling.
- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.

Common (may affect up to 1 in 10 people)

- Loss of appetite.
- Reduced sex drive.
- Depression.
- Feeling sleepy.
- 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).
- Weight gain.
- Chest pain.
- Reduced heart function.
- Heart attack.

Rare (may affect up to 1 in 1,000 people)

- Increased skin sensitivity to sunlight.

Your doctor may do blood tests to check for any changes to your blood.

Do not be concerned by this list of possible side effects. You may not get any of them.

5. HOW TO STORE BICALUTAMIDE TABLETS 50MG

- Keep your tablets in the container they came in.
- Do not store above 30°C.
- Keep this medicine out of the sight and reach of children.



- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bicalutamide tablets 50mg contains

The active substance is bicalutamide. Each tablet contains 50 mg of bicalutamide.

The other ingredients are lactose monohydrate (see section 2, Bicalutamide contains lactose), magnesium stearate, hypromellose, macrogol 300, povidone, sodium starch glycolate and titanium dioxide (E171).

What Bicalutamide tablets 50mg looks like and contents of the pack

White colored, round shaped, biconvex film coated tablets, debossed with 2 on one side and H on the other side.

Bicalutamide tablets 50mg are available in:

Container pack: 30's HDPE Container & 3 x10's Blister pack (Alu-PVC)

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
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Telangana

Country: INDIA



Manufacturer:

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