

Package leaflet: Information for the patient

Bicalutamide Fair-Med 50 mg Film-coated tablets Bicalutamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Bicalutamide Fair-Med is and what it is used for
2. What you need to know before you take Bicalutamide Fair-Med
3. How to take Bicalutamide Fair-Med
4. Possible side effects
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1. What Bicalutamide Fair-Med is and what it is used for

Bicalutamide Fair-Med contains a medicine called bicalutamide. This belongs to a group of medicines called 'anti-androgens'. It works by blocking the effect of the male sex hormones (androgens) and inhibits cell growth in the prostate.

Bicalutamide Fair-Med is used to treat advanced prostate cancer. It is taken together with an additional hormone treatment (called LHRH analogue) or with accompanying surgical removal of the testicles.

2. What you need to know before you take Bicalutamide Fair-Med

Do not take Bicalutamide Fair-Med:

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in Section 6).
- if you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole).
- if you are a woman.

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

Bicalutamide Fair-Med must not be given to children and adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide Fair-Med if:

- you have problems with your liver. The drug should then only be taken after your doctor has carefully considered possible benefits and risks. Your doctor will regularly perform tests of liver function (bilirubin, transaminases, alkaline phosphatase). If severe disturbances to liver function develop, treatment with Bicalutamide Fair-Med should be discontinued.
- your renal function is severely impaired. The drug should only be taken after your doctor has carefully considered possible benefits and risks.

- you suffer from heart disease including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. If this is the case, your doctor should regularly monitor your heart function.
- You have diabetes and are already taking an 'LHRH analogue'. These include goserelin, buserelin, leuprorelin and triptorelin.

If you go into hospital, tell the medical staff that you are taking Bicalutamide Fair-Med.

Other medicines and Bicalutamide Fair-Med

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Bicalutamide Fair-Med if you are already taking any of the following medicines:

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

Bicalutamide Fair-med might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

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

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants, e.g. warfarin).
- Ciclosporin (to suppress your immune system).
- Cimetidine (to treat stomach ulcers)
- Ketoconazole (used to treat fungal infections of the skin and nails)
- Calcium channel blockers (to treat high blood pressure or some heart conditions).

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

Bicalutamide Fair-Med is contra-indicated in females and must not be given to pregnant or breast-feeding mothers.

Bicalutamide Fair-Med may induce a period of subfertility or infertility in man.

Driving and using machines

- Bicalutamide Fair-Med is not likely to affect you being able to drive or use any tools or machines.
- However, there is a possibility that these tablets could make you feel dizzy or drowsy. If you are affected in this way, you should not drive or operate machinery.

Bicalutamide Fair-Med contains lactose monohydrate

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 Fair-Med

Always take this medicine exactly as your doctor or pharmacist 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 Fair-Med than you should

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

If you forget to take Bicalutamide Fair-Med

- If you forget to take a dose, skip the missed dose and take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

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

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) and raised transaminases. 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’.

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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 (oedema).
- 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 (cardiac failure).
- 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. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Bicalutamide Fair-Med

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 after <EXP>. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Fair-Med contains

- The active substance is bicalutamide. Each tablet contains 50 mg bicalutamide.
- The other ingredients are:
Tablet core: Lactose Monohydrate, Povidone K- 25, Sodium starch glycolate (type A), Magnesium Stearate
Coating: Hypromellose (5cP), Titanium dioxide (E171), Propylene Glycol

What Bicalutamide Fair-Med looks like and contents of the pack

White, round, biconvex film coated tablets.

PVC/ PVDC/Aluminium blisters.

10, 14, 20, 28, 30, 40, 50, 56, 60, 80, 84, 86, 90, 98, 100, 140, 200, 280 film coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fair-Med Healthcare GmbH

Planckstrasse 13, 22765 Hamburg

Germany

Manufacturer

Genepfarm S.A.

18km Marathon Avenue, 15351 Pallini Attikis

Greece

or

Remedica Ltd

Limassol Industrial Estate, P.O. Box 51706,

CY-3508 Limassol

Cyprus

or

Pharmadox Healthcare Ltd

KW 20A – Kordin Industrial Park – Paola, PLA 3000

Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

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| Cyprus: | Bicalutamide Fair-Med |
| Denmark: | Bicalutamid Fair-Med |
| Germany: | Bicalutamid Fair-Med Healthcare 50mg Filmtabletten |
| Ireland: | Bicalutamide Fair-Med 50mg Film-coated Tablets |
| Malta: | Bicalutamide Fair-Med 50mg Film-coated Tablets |
| Netherlands: | Bicalutamide Fair-Med 50mg, filmomhulde tabletten |
| Poland: | Bicalutamide Fair-Med |
| Portugal: | Bicalutamida Fair-Med 50mg, Comprimidos revestidos por película |

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