PACKAGE LEAFLET: INFORMATION FOR THE USER
Bicalutamide Hikma 50 mg film coated tablets.
Bicalutamide

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT BICALUTAMIDE HIKMA 50 MG IS AND WHAT IT IS USED FOR

Bicalutamide Hikma 50 mg is used for the treatment of advanced prostate cancer. It is taken together with a drug known as an luteinising hormone-releasing hormone (LHRH) analogue which reduces the levels of androgens (male sex hormones) within the body, or with accompanying surgical removal of the testicles. The active ingredient of Bicalutamide Hikma 50 mg, bicalutamide, belongs to a group of medicines called non-steroidal anti-androgens. It blocks the undesired effect of the male sex hormones (androgens) and inhibits cell growth in the prostate in this way.

2. BEFORE YOU TAKE BICALUTAMIDE HIKMA 50 MG

Do not take Bicalutamide Hikma 50 mg
- if you are allergic (hypersensitive) to bicalutamide or any of the other ingredients of Bicalutamide Hikma 50 mg
- if you are already taking terfenadine or astemizole (for hay fever or allergy), or cisapride (for stomach disorders).

Bicalutamide Hikma 50 mg should not be taken by women or must not be given to children or adolescents.

Take special care with Bicalutamide Hikma 50 mg
- if your liver function is moderately or severely impaired. The drug should then only be taken after your doctor has carefully considered possible benefits and risks. If this is the case, your doctor will regularly perform tests of liver function. If severe disturbances to liver function develop, treatment with Bicalutamide Hikma 50 mg should be discontinued.
- if your renal function is severely impaired. The drug should then only be taken after your doctor has carefully considered possible benefits and risks.
- if you suffer from heart disease. If this is the case, your doctor should regularly monitor your heart function.
- if you have diabetes and are already taking an 'LHRH analogue'. These include goserelin, buserelin, leuprorelin and triptorelin.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take Bicalutamide Hikma 50 mg together with one of the following medicines, the effect of bicalutamide as well as the other medicine may be influenced. Please speak to your doctor before taking any of these medicines together with Bicalutamide Hikma 50 mg.

- warfarin or any similar medicine to prevent blood clots,
- terfenadine or astemizole (for hay fever or allergy),
- cisapride (for stomach disorders),
- ciclosporin (used to suppress your immune system to prevent and treat rejection of a transplanted organ or bone marrow),
- calcium channel blockers (used to treat high blood pressure or some heart conditions)
- cimetidine (used to treat stomach ulcers),
- ketoconazole (used to treat fungal infections of the skin and nails)."

Taking Bicalutamide Hikma 50 mg with food and drink

Bicalutamide Hikma 50 mg can be taken before, during or after a meal, but also you can take them without food. The film coated tablet should be swallowed with some water or another liquid.

Pregnancy and breast-feeding
Bicalutamide Hikma 50 mg is contra-indicated. in females and must not be given to pregnant or breast-feeding mothers.

Driving and using machines

Bicalutamide Hikma 50 mg is unlikely to adversely affect your ability to drive a car or to operate machinery. However, some people may occasionally feel dizzy or drowsy after taking Bicalutamide Hikma 50 mg. If this happens to you, you should exercise caution when carrying out such tasks. If you suffer from dizziness or drowsiness you would be best advised not to carry out such tasks. However if you still drive a car or use machines you should exercise extra caution.

Important information about some of the ingredients of Bicalutamide Hikma 50 mg

Bicalutamide Hikma 50 mg contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor immediately.

3. HOW TO TAKE BICALUTAMIDE HIKMA 50 MG

Always take Bicalutamide Hikma 50 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one film coated tablet daily. It is better to take the film coated tablet at the same time every day. The film coated tablet should be swallowed with some water or another liquid without being chewed and can be taken with or without food.

Children and adolescents
This medicine is not recommended for patients under the age of 18 years.

If you take more Bicalutamide Hikma 50 mg than you should

If you take more than your normal dose, contact your doctor. In the case of an overdose, contact the nearest hospital immediately. If possible, take your film-coated tablets or the box with you to show the doctor what you have taken.

If you forget to take Bicalutamide Hikma 50 mg

If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a frogottn dose. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Bicalutamide Hikma 50 mg

Do not stop taking your film coated tablets, even if you are feeling well, unless your doctor tells you.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bicalutamide Hikma 50 mg can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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Side effects that are very common (estimated frequency is more than 1 person out of 10):

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- dizziness
- hot flush
- abdominal pain
- constipation
- nausea
- blood in urine
- gynaecomastia (development of breasts in men)
- breast tenderness
- weakness
- oedema (swelling due to fluid)

Side effects that are common (estimated frequency is less than 1 person out of 10 but more than 1 out of 100):

- somnolence
- indigestion
- flatulence
- alopecia
- hirsutism (hairiness) / hair re-growth
- rash
- dry skin
- itching
- impotence (erectile dysfunction)
- chest pain
- decreased appetite

- decreased libido
- depression
- myocardial infarction
- heart failure
- hepatotoxicity
- jaundice
- increased of liver proteins
- weight gain

Side effects that are uncommon (estimated frequency is less than 1 person out of 100 but more than 1 out of 1000)
- hypersensitivty
- angioedema (skin blistering)
- urticaria
- inflammation of the lungs called interstitial lung disease

Rare side effects (estimated frequency is less than 1 person out of 1000 but more than 1 out of 10,000):
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- liver failure

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE BICALUTAMIDE HIKMA 50 mg

Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions.

Do not use Bicalutamide Hikma 50 mg after the expiry date which is stated on theblister and carton. The expiry date refers to the last day of that month.

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

6. FURTHER INFORMATION

What Bicalutamide Hikma 50 mg contains

- The active substance is bicalutamide. Each film-coated tablet contains 50mg bicalutamide.

The other ingredients are:
Tablet core:
Lactose monohydrate, Povidone K- 25, Sodium starch glycolate Type A, Magnesium Stearate.

Film coating:
Opadry OY-S-9622 which contains Hypromellose 5cp (E464), Titanium dioxide (E171) and Propylene Glycol.

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

Bicalutamide Hikma 50 mg is supplied as white, round, biconvex film coated tablets. The film coated tablets are packed in blister packs containing 10, 28, 30, and 90 tablets contained in a carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Hikma Farmacêutica S.A.
Estrada do Rio da Mó No 8
8A&8B Fervença
2705-906
Terrugem SNT
Portugal

Manufacturer
Genepharm S.A
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This medicinal product is authorised in the Member States of the EEA under the following names:

AT: Bicalutamid Hikma
DE: Ribocadex
ES: Bicalutamide Hikma
IE: Bicalutamide Hikma
IT: Bicalutamide Hikma
NL: Bicalutamide Hikma
PT: Bicalutamide Hikma
UK: Bicalutamide

This leaflet was last approved in {MM/YYYY}.