

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Casodex® 150 (Tablet)

Read this entire leaflet carefully before you start taking CASODEX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

CASODEX has been prescribed for you personally and you should not share your CASODEX with other people. It may harm them, even if their symptoms are the same as yours.

WHAT CASODEX 150 CONTAINS:

Each tablet contains 150 mg bicalutamide.

The other ingredients are lactose monohydrate, sodium starch glycollate, polyvidone, magnesium stearate, methylhydroxypropylcellulose , polyethylene glycol and titanium dioxide.

Contains sugar (lactose monohydrate).

WHAT CASODEX 150 IS USED FOR:

CASODEX 150 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.

BEFORE TAKING CASODEX 150:

Do not take CASODEX 150:

- If you are allergic to bicalutamide or any other ingredients of CASODEX 150.
- In women and children.

Take special care with CASODEX 150 in the following instances:

Before taking CASODEX 150 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 CASODEX 150 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 CASODEX 150 with food and drink:

Do not take CASODEX 150 with grapefruit juice as this may affect how CASODEX 150 works.

Pregnancy and Breastfeeding:

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

Driving and using machinery:

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

Important information about some of the ingredients of CASODEX 150:

Lactose Warning:

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

Patients with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take CASODEX150.

Taking other medicines with CASODEX 150:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

If you are taking medicines on a regular basis, using CASODEX 150 at the same time with another medicine may cause undesirable interactions, please consult your doctor, pharmacist or other health care professional for advice.

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

- Midazolam, astemizole, cisapride, and ciclosporine
- Warfarin

HOW TO TAKE CASODEX 150:

- Follow your doctor, pharmacist, or other health care professional's instructions on how to take CASODEX 150 and ask them if you are unsure.
- Do not share medicines prescribed for you.
- If you feel that the effect of CASODEX 50 is too strong or too weak, tell your doctor or pharmacist.

The usual dose:

Adults: Take one tablet once a day.

If you forget to take CASODEX 150:

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.

If you take more CASODEX 150 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.

POSSIBLE SIDE EFFECTS:

CASODEX 150 can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Contact your doctor or seek medical help immediately if you experience any of the following, side effects that may occur frequently:

- 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 CASODEX 150 get an inflammation of the lungs called interstitial lung disease.
- 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.

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

The following side effects may occur frequently:

- 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

CASODEX 150 may also be associated with changes in your blood which may require your doctor to do certain blood tests.

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

STORING AND DISPOSING OF CASODEX 150:

How do you store CASODEX 150?

You should keep your tablets stored at or below 30°C.

Store all medicines out of reach of children.

How to dispose of CASODEX 150?

Take all unused or expired medicines to your pharmacist, doctor or other health care professional.

PRESENTATION OF CASODEX 150:

CASODEX 150 tablets are stored in cartons containing clear PVC/aluminium foil blister packs of 30 tablets.

IDENTIFICATION OF CASODEX 150:

A round, white, coated tablet with “Casodex 150” on the one side and a logo on the other side.

REGISTRATION NUMBER:

33/21.12/0081

NAME AND ADDRESS OF REGISTRATION HOLDER:

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