PART III: CONSUMER INFORMATION

[Pr]PRO-BICALUTAMIDE - 50
bicalutamide tablets

This leaflet is part III of a three-part "Product Monograph" published when PRO-BICALUTAMIDE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-BICALUTAMIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-BICALUTAMIDE is used in the treatment of advanced prostate cancer in combination with other drugs (LHRH analogues) which reduce the levels of androgens in the body or surgery.

What it does:
Androgens are male sex hormones within the body which can cause tumour growth within the prostate. PRO-BICALUTAMIDE belongs to a group of medicines called non-steroidal antiandrogens. This means that PRO-BICALUTAMIDE interferes with some of the actions of androgens to prevent the tumour from growing.

What are the Stages of Prostate Cancer:
- Localized disease- the early stages of disease when prostate cancer is confined to the prostate gland
- Locally advanced disease- the disease progresses and the cancer spreads to other tissues within the pelvis
- Advanced or metastatic disease- the disease progresses to other parts of the body

The PSA (Prostate Specific Antigen) test is a simple blood test for a protein produced by the prostate (PSA). This test has helped in the detection of prostate cancer resulting in an increase in the number of men whose prostate cancer is detected at an early stage.

What are the Treatment Options for Localized Prostate Cancer:
The optimal treatment for a given individual will depend on the specific circumstances of his case. For localized disease, patients are usually offered one of the following:
- Surgery to remove the prostate
- Targeted radiotherapy to kill the cancer cells in the prostate
- No treatment initially (watchful waiting) whereby the patient is monitored until there are signs of progression before treatment is started.

When it should not be used:
- Do not take PRO-BICALUTAMIDE if you have early phase (localized) prostate cancer requiring watchful waiting.
- Do not take PRO-BICALUTAMIDE if you are allergic to bicalutamide or any of the nonmedicinal ingredients in PRO-BICALUTAMIDE.
- PRO-BICALUTAMIDE must not be taken by women, including pregnant women or mothers who are breast feeding their babies.
- PRO-BICALUTAMIDE must not be given to children.

What the medicinal ingredient is:
Bicalutamide.

What the nonmedicinal ingredients are:
Colloidal silicon dioxide, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethelyne glycol, povidone, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide, triethyl citrate

What dosage forms it comes in:
Tablets: 50 mg

WARNINGS AND PRECAUTIONSu

- **PRO-BICALUTAMIDE should only be prescribed by a doctor experienced with the treatment of prostate cancer.**
- **PRO-BICALUTAMIDE 150 mg/day dose should not be used.**
- **PRO-BICALUTAMIDE may rarely be associated with liver failure; some cases have been fatal.**
- **PRO-BICALUTAMIDE may be associated with uncommon cases of interstitial lung disease; some cases have been fatal.**

BEFORE you use PRO-BICALUTAMIDE talk to your doctor or pharmacist if:
- You have liver disease.
- You have lung disease.
- You have low bone mineral density (BMD)

- You have low red blood cell count (anemia).
- You have heart disease, or have a heart condition called "long QT syndrome" or family history of this heart condition

If you go into hospital let the medical staff know you are taking PRO-BICALUTAMIDE.

PRO-BICALUTAMIDE may make you feel sleepy. Do not drive or use machines until you know how the drug affects you.

INTERACTIONS WITH THIS MEDICATION

Please inform your doctor if you are taking or have recently taken any other medicines, even those not prescribed.

- In particular please inform your doctor if you are taking oral anti-coagulants (to prevent blood clots)
- If you are taking any medicines that may increase the risk of having an abnormal heart rhythm.

PROPER USE OF THIS MEDICATION

Follow your doctor's instructions about when and how to take your tablets. Ask your doctor or pharmacist if you are not sure.

- The usual adult dose is 50 mg daily.
- Swallow the tablet(s) whole with a drink of water
- Try to take your dose at the same time each day.

During the first few months of use, you may be monitored by your physician for signs of changes in your liver function. In approximately 2.0% of patients, such changes may lead to withdrawal of therapy.

If you experience a rise in PSA while taking PRO-BICALUTAMIDE, your physician may discontinue PRO-BICALUTAMIDE for several weeks in order to monitor your condition off treatment.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

You should take PRO-BICALUTAMIDE as prescribed. However, if you miss a dose, do not take an extra dose; just resume your usual schedule.

SIDE EFFETS AND WHAT TO DO ABOUT THEM

Like all medicines, PRO-BICALUTAMIDE 50 mg can have side effects.

Side effects that are very common (more than 10 in every 100 patients are likely to have them):

- dizziness
- nausea
- hot flushes
- feeling weak
- decreased red blood cell count (anemia)
- puffiness/swelling
- constipation

Side effects that are common (1 to 10 in every 100 patients are likely to have them):

- loss of appetite
- reduced sex drive
- depression
- sleepiness
- indigestion
- flatulence
- loss of hair or hair re-growth
- rash
- itching
- dry skin
- impotence
- chest pain
- tender or enlarged breast tissue
- weight gain
- heart failure
- heart attack

Occasionally PRO-BICALUTAMIDE may be associated with changes in your blood which may require your doctor to do certain blood tests.

SERIOUS SIDE EFFETS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom/effect	**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency medical attention**
	Only if severe	**In all cases**	
Very Common (more than 10 in every 100 patients are likely to have them)			
Blood in urine		✓	
Abdominal pain		✓	
Common (1 to 10 in every 100 patients are likely to have them)			
Yellow skin and eyes (jaundice). These may be symptoms of liver damage.		✓	
Heart failure (reduced heart function)		✓	
Heart attack		✓	
Uncommon (1 to 10 in every 1000 patients are likely to have them)			
Serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. Some patients taking bicalutamide 50 mg 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		✓	

Tell your doctor or pharmacist if you think you have any of these or any other problems with your tablets.

This is not a complete list of side effects. For any unexpected effects while taking PRO-BICALUTAMIDE, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep your tablets in the container they came in.
- Do not take your tablets after the expiry date on the container. Dispose of them in an appropriate way.
- Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.
- Keep your tablets between 15°C and 30°C. Protect from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, http://www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée, Laval, Québec, H7L 3W9

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