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**INFORMATION ON BICALUTAMIDE FOR WOMEN**  
(for patients of Dr Donovan's practice)

**What is Bicalutamide & how does it work?**

- Bicalutamide is an oral medication (pill) that is used "off label" for treating androgenetic alopecia in women. Generally, the use of bicalutamide is limited to post-menopausal women but exceptions to exist and sometimes Dr Donovan will prescribe for premenopausal women.
- It is approved by the FDA for treating prostate cancer in men. Doses 50 -150 mg daily may be used for cancer treatment.
- A popular trade name of Bicalutamide is known as "Casodex" and therefore you may hear the medication commonly referred to as Casodex.
- Bicalutamide is sometimes prescribed for women's hair loss by dermatologists around the world.
- The drug blocks the effects of the male hormone (androgen) and is said to be a pure nonsteroidal androgen receptor blocker. It is closely related to another antiandrogen called flutamide. Although flutamide was once used for acne and even hair loss, we don't use flutamide much anymore because we believe safer options are available.
- Women with androgenetic hair loss and frontal fibrosing alopecia may benefit from bicalutamide

**Does Bicalutamide help with hair loss?**

- Bicalutamide can be helpful at doses 12.5 mg to 50 mg 3 to 7 times per week.
- It is important to check Dr. Donovan's recommendation. The use may not be daily and may not be the full pill.

**How long does the drug need to be used?**

- For women with genetic hair loss, Bicalutamide only works while it's taken. It must be taken forever to maintain the benefits. If women with genetic hair loss decide to stop Bicalutamide, the benefits are lost in 6 months and hair density goes back to the way it was before starting the drug.
- For women with frontal fibrosing alopecia, Bicalutamide helps calm down or 'inactive' the disease. Unlike genetic hair loss, it may be possible for some women with frontal fibrosing alopecia to stop their Bicalutamide at some point and not lose further hair. This is assuming they do not have any androgenetic alopecia. If they do have androgenetic alopecia, the drug might need to be used forever.

# INFORMATION ON BICALUTAMIDE FOR WOMEN

## What are the side effects of Bicalutamide for women?

The following are side effects to be aware of :

- Increased liver enzymes (up to 11% have this side effect)
- Swelling in the feet and fluid retention ( 3 %)
- Gastrointestinal symptoms (2 %)
- Enlargement of breast tissue and sometimes breast tenderness 1-2 %
- Mood changes (anxiety & depression) - 0.5%
- Decreased libido (sex drive) – 0.5 %
- Photosensitivity 0.5 %
- Anemia and changes in blood counts (rare)
- Difficulty concentrating
- Bicalutamide cannot be used by pre-menopausal women who are planning pregnancy or may become pregnant. Bicalutamide can seriously harm a baby if a female user were to get pregnant
- Weight gain
- Fatigue
- Constipation and/or Diarrhea
- Skin Rashes and Skin Itching
- Muscle pain (and increased muscle enzymes such as CK in the blood)
- Hair shedding
- Abnormal uterine bleeding (very rare)
- Cough (lung issues) – very rare
- Heart rhythm issues (especially with drugs that prolong QT intervals)

## IMPORTANT POINTS TO REMEMBER:

- Bicalutamide is prescribed by experienced doctors around the world for post-menopausal women with hair loss. Your pharmacist might not know this and may question why you are receiving this medication.
- You cannot donate blood while taking Bicalutamide. If a pregnant woman were to need blood, the presence of Bicalutamide in the donated blood could harm her pregnancy.

## Are blood tests needed when starting or while on Bicalutamide?

Yes. Baseline liver enzymes, electrolytes (Potassium, magnesium, calcium), CBC are needed before starting bicalutamide and then liver enzymes and CBC need to be checked monthly for 3-4 months and then 1-2 months after any dose change.

An ECG should be done before starting in there are any concerns about QT interval.

## **Who is not a good candidate for oral bicalutamide for hair loss?**

### **The following patients may not be good candidates:**

- Patients in whom the diagnosis is not clear
- Female patients who plan to become pregnant or pregnancy is possibility
- Female patients who are breastfeeding
- Patients who do not understand risk of this medication
- Patients unwilling or unable to have blood test monitoring
- Patients unwilling or unable to attend follow up appointment
- Patients with liver disease
- Patients who have interstitial lung disease
- Patients with osteoporosis
- Patients using drugs that prolong QT or have known long QT intervals
- Patients with severe anemia
- Patients with heart disease
- Patients who use drugs that are metabolized by CYP 3A4. Bicalutamide is an inhibitor of CYP 3A4; therefore, caution should be used when this drug is co-administered with CYP 3A4 substrates.

## **WHAT STUDIES CAN I REVIEW FOR FURTHER INFORMATION ?**

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Ismail et al. Safety of Oral Bicalutamide in female pattern hair loss: A retrospective review of 316 patients. J Am Acad Dermatol. Nov 2020

Fernandez-Nieto et al. Bicalutamide: A potential pure anti-androgens with Potential Benefit in Treating Female Androgenetic Alopecia. J Am Acad Dermatol. Nov 2020 in 435 patients. J Am Acad Dermatol Nov 2020

# DONOVAN

## BICALUTAMIDE CONSENT FORM FOR DR. DONOVAN'S PATIENTS

At the Donovan Hair Clinic, it is very important to us that you understand the benefit as well as potential side effects. Please initial beside each of the following to indicate that you have reviewed these issues with Dr. Donovan. **I understand and acknowledge that :**

\_\_\_\_\_ I am a patient of Dr. Donovan and have had an appointment with him in the last 6 months

\_\_\_\_\_ Bicalutamide pills are 50 mg in each pill. I understand that Dr. Donovan may require me to only use this medication a few times per week and may ask that I break the pill.

\_\_\_\_\_ Bicalutamide may be associated with mood changes such as depression (approx. 1 % of users) and possibly other symptoms like anxiety and memory problems and 'brain fog'

\_\_\_\_\_ Bicalutamide may be associated with sexual side effects, including decreased libido.

\_\_\_\_\_ Antiandrogens have rarely been associated with permanent and long lasting sexual dysfunction in men. However, I understand that this has not been reported with bicalutamide in women to date but nevertheless could be possible.

\_\_\_\_\_ Bicalutamide may be associated with enlargement of breast tissue and breast tenderness

\_\_\_\_\_ Bicalutamide may be associated with weight gain in some users.

\_\_\_\_\_ Bicalutamide users should not donate blood

\_\_\_\_\_ Women of childbearing potential should never handle broken (crushed) Bicalutamide tablets.

\_\_\_\_\_ Bicalutamide users should do regular self-breast exams to check for lump. I understand that at present there is no definitive evidence to link Bicalutamide with breast cancer.

\_\_\_\_\_ Should I develop side effects from Bicalutamide I will contact Dr. Donovan. I understand that I will need to stop the medication if Dr Donovan advises me to stop.

\_\_\_\_\_ I have received a copy of the Bicalutamide Information Sheet (page 1-2).

\_\_\_\_\_ I understand that if I use bicalutamide I will require follow up from a dermatologist at least once every 9-12 months depending on my exact situation.

\_\_\_\_\_  
NAME

\_\_\_\_\_  
DATE (DAY/MONTH/YEAR)

\_\_\_\_\_  
SIGNATURE

PLEASE SEND MY SCRIPT TO: