CONSENT FORM FOR ORAL MINOXIDIL

What is oral minoxidil?

Minoxidil is well known as a topical lotion or foam for treating hair loss. However, it is also an oral medication (tablet/pill) that has been used in the past for treating high blood pressure. One of the side effects that was notice in patients using the tablet for high blood pressure is that they had an increased amount of hair on the body and scalp. This prompted further study and ultimately the development of topical minoxidil.

Both oral and topical minoxidil exist today. Topical minoxidil is sold under many names including brand names such as Rogaine and several generics as well. Oral minoxidil requires a prescription and more follow up monitoring.

The licensed indication for oral minoxidil is to treat severe hypertension (high blood pressure) that does not respond to standard treatments.

Patients taking minoxidil for blood pressure control use 10-40 mg daily and the maximum dose is 100 mg.

The dose used for hair loss is 0.25 mg to 1 mg – up to 40 to 160 times less than the blood pressure dose

Oral minoxidil has been less well studied compared to topical minoxidil. Nevertheless, there is evidence for benefit in androgenetic alopecia, hair fragility disorders, alopecia areata and chemotherapy related hair loss.

How does minoxidil help promote hair growth?

Despite years of use, the precise mechanism by which minoxidil helps hair growth is not fully known. It is believed that it helps increase blood flow in the scalp. It may also directly affect the hair follicle machinery by affecting ion channels (potassium channels) inside the hair follicle.
What is the dose that Dr. Donovan prescribes?

Dr. Donovan will advise you on the precise dose he would like you to use. This ranges from 0.25 mg daily to up to 2.5 mg daily. Typically doses are between 0.25 mg and 1.25 mg.

For low doses, a pharmacy will need to assist in compounding the medication. With doses that are higher, a 2.5 mg standard tablet can simply be broken into 4 pieces to give 0.625 mg pieces. The pharmacist will provide a pill cutter to assist in cutting the tablets into quarters to give 0.625 mg pieces.

Only take the amount that Dr. Donovan has prescribed.

Who should not use oral minoxidil?

The following patients should not use (called “contraindications”)

1. Do not use oral minoxidil if you are pregnant or trying to conceive. **All** women of childbearing potential must use effective contraception during the treatment course and for 1 month after to prevent pregnancy. Dr. Donovan will require a negative pregnancy test result is required before treatment can start.
2. Patients over 60 years of age.
3. Patients with underlying chronic health issues, especially kidney, heart and liver problems.
4. Patients with heart disease include those with previous heart attacks but also those with angina, heart failure and rhythm problems
5. Patients with pheochromocytomas
6. Patients with porphyria
7. Patients who have not used other standard hair loss treatments first (see below)
8. Dr. Donovan does not prescribe in patients with ANA positivity (1:640 level) or those with underlying autoimmune disease.
9. Patients with low blood pressure to begin with or those using anti-hypertensives.
DR. DONOVAN’S CRITERIA FOR ORAL MINOXIDIL USE:

Please note that Dr. Donovan prescribes oral minoxidil only under specific circumstances. It is not a treatment for everyone:

MEN

Dr. Donovan will consider oral minoxidil in men age 20-60 who meet the following criteria:

1. The patient has used topical minoxidil in the past and did not have a satisfactory results or did not wish to continue
2. The patient has used oral finasteride in the past or was unable to use or did not wish to start.
3. The patient is aware of options such as topical antiandrogens, low level laser or PRP and has considered these.
4. The patient has considered the possibility of a hair transplant in his overall long term plan
5. The patient is healthy and has none of the following health issues:
   a. Kidney disease
   b. Heart disease of any kind
   c. Liver disease
   d. Pheochromocytoma
   e. Porphyria
6. The patient understands the potential side effects
7. The patient understands this is a lifelong treatment
8. The patient has a normal TSH and ferritin and urinalysis and creatinine
9. The patient has a normal ECG (heart tracing)
10. The patient has reviewed and submitted the consent form
11. The patient agrees to frequent monitoring of his blood pressure every week for the first month and then monthly with submission of results to Dr. Donovan
12. The patient agrees to monitor her weight every 3 days when starting for the first months and report and increases of more than 4 pounds to Dr. Donovan
13. The patient agrees to follow up appointments with Dr. Donovan every 6 months. Dr. Donovan is not permitted to renew prescriptions for oral minoxidil without a full review.
DR. DONOVAN’S CRITERIA FOR ORAL MINOXIDIL USE (continued):

WOMEN

Dr. Donovan will consider oral minoxidil in women age 30-60 who meet the following criteria

1. The patient has used topical minoxidil in the past and did not have a satisfactory results or did not wish to continue
2. The patient has considered use of oral anti-androgens such as spironolactone
3. The patient is aware of options such as low level laser or PRP and has considered these
4. The patient has considered the possibility of a hair transplant in his overall long term plan
5. The patient is healthy and has none of the following health issues
   a. Kidney disease
   b. Heart disease of any kind
   c. Liver disease
   d. Pheochromocytoma
   e. Porphyria
6. The patient is not pregnant at present and does not plan to have additional children.
7. The patient has a normal TSH and ferritin above 35 and urinalysis and creatinine
8. The patient has a normal ECG (heart tracing)
9. The patient understands the potential side effects
10. The patient understands this is a life-long treatment.
11. The patient has reviewed and submitted the consent form.
12. The patient agrees to frequent monitoring of her blood pressure every week for the first month and then monthly with submission of results to Dr. Donovan
13. The patient agrees to monitor her weight every 3 days when starting for the first months and report and increases of more than 4 pounds to Dr. Donovan
14. The patient agrees to follow up appointments with Dr. Donovan every 6 months. Dr. Donovan is not permitted to renew prescriptions for oral minoxidil without a full review.
What are the possible side effects of ORAL MINOXIDIL??

Side effects with low dose minoxidil are much less than for the higher doses originally used to treat high blood pressure.

The most common side effect in practice is increased hair on the upper lip in 25-35 % of women. Other less common side effects are typically headaches, ankle swelling, hives. Shedding is not very common.

The most common side effects of low dose oral Minoxidil can be remember by the 4 letter memory tool “HAIR”

- **H**eadaches and dizziness – 5 %
- **A**nkle edema - 2-3 %
- **I**ncreased hair on face (lip) – 25-35 %
- **R**ashes and urticaria (hives) - < 2 %
Side effects seen with higher doses are well known from the past. These include:

1. Weight gain from fluid retention
2. Swelling of the ankles (from fluid retention)
3. Hair shedding in the first 6-9 weeks (common and not a cause for stopping minoxidil)
4. Increased heart rate and palpitations
5. Shortness of breath
6. Chest pain
7. Low blood pressure (may causes one to feel dizzy or faint)
8. Fluid around the heart (Pericarditis / pericardial effusion)
9. Increased hair on the body (develops in 3-6 weeks).
10. Skin rashes
11. Nausea and vomiting
12. Breast tenderness (less than 1 %)
13. Blood test abnormalities
14. Lowered blood pressure with alcohol use
15. Increased heart rate with caffeine and caffeinated products (cold and flu)
16. Lab abnormalities (rare) including lower platelets and white cells.

**Can oral minoxidil be taken with other pills and medications?**

Oral minoxidil could potentially interact with a number of medications. Please advise Dr Donovan of all medications you take and any new ones in the future. This includes all medications but particularly other blood pressure and heart medications. All physicians and health care providers you encounter in the future must be informed you take oral minoxidil.

**What if I develop side effects that worry me?**

If you develop mild side effects during our office opening times, please contact us at 604.283.9299 or via email at vancouveroffice@donovanmedical.com

If you have serious side effects or have side effects are hours, you will want to visit your emergency department or walk in clinic.
One should STOP minoxidil and seek help if you develop any of the following side effects

1. Heart rate 20 beats higher than your normal ‘resting’ level
2. Ankle swelling
3. Weight gain of more than 4 pounds
4. Shortness of breath or chest pain
5. Feeling light-headed or dizzy

**What are the typical ingredients in minoxidil tablets?**

We would recommend you check with your pharmacist as this could change. Inactive ingredients frequently include cellulose, corn starch, lactose, magnesium stearate, silicon dioxide.

**My pharmacist tells me that I should be using a diuretic like hydrochlorothiazide or a beta blocker like propranolol when using minoxidil pills. Is this correct?**

Not for most, no. This applies to men and women who are using higher doses of minoxidil such as 5 and 10 mg (or more). The dose for hair loss is 0.25 mg to 2.5 mg.
MINOXIDIL CONSENT FORM – PAGE 1

Please initial next to each of the following AND sign the bottom.

1. I have read the Minoxidil Handout (above) provided by the clinic and have had all my questions answered by Dr. Donovan.

   __________ INITIAL

2. I understand that the doses I will be using are very small compared to the doses used to treat blood pressure problems

   __________ INITIAL

3. I understand that if I do get an improvement, that this will be a lifelong treatment and I will need to renew prescriptions on minoxidil periodically throughout the year to maintain my effect. If I choose to stop treatments, I understand that my hair will return to their previous appearance over several weeks to months.

   __________ INITIAL

4. I attest that I do not currently have heart disease or kidney disease

   __________ INITIAL

5. I attest that I have reviewed and considered other treatment options including topical minoxidil, anti-androgens, laser, PRP and hair transplantation

   __________ INITIAL
6. I understand that if I am to have any procedure or visit with another health care provider (dentist, eye doctor, etc) in the future I will inform him or her that I use oral minoxidil

INITIAL

7. I agree to stop using oral minoxidil right away and advise Dr. Donovan if I develop side effects including weight gain of more than 3 pounds, dizziness, chest pain, shortness of breath, ankle swelling, rapid heart rate. I understand that if these side effects are worrisome or troublesome I should go to the emergency department rather than contact Dr. Donovan.

INITIAL

8. I understand that if I have any questions or concerns about minoxidil or a side effect I am experiencing I am to bring them to Dr. Donovan’s attention immediately when I have this side effect.

INITIAL

9. I understand that side effects are possible with any medication. I am aware of the side effects of minoxidil that have been reviewed with me. I am also aware that other rare side effects are possible with any medication and that a doctor and pharmacist might not be able to advise of every single possible side effect.

INITIAL
SIDE EFFECTS. Please initial next to each to indicate you understand the possible array of side effects

_____ Weight gain from fluid retention
_____ Swelling of the ankles from fluid retention
_____ Hair shedding in the first 6-9 weeks
_____ Increased heart rate and palpitations
_____ Shortness of breath
_____ Chest pain
_____ Low blood pressure (may causes one to feel dizzy)
_____ Increased hair on the body (develops in 3-6 weeks).
_____ Skin rashes
_____ Nausea and vomiting
_____ Breast tenderness (less than 1 %)
_____ Blood test abnormalities
_____ Lowered blood pressure with alcohol use
_____ Increased heart rate with caffeine and caffeinated products (cold and flu)
_____ Lab abnormalities (rare) including lower platelets and white cells.
10. I understand that I will require periodic follow up appointments with Dr. Donovan when using minoxidil, and generally these are every 6 months. This can be in person or by phone. If I choose a phone consultation I must submit photos of my scalp. At minimum, I understand that Dr. Donovan requires q 6 months follow up for all oral minoxidil users and that I am responsible for appointment fees for such follow up appointments. I understand that if I choose to have by follow up appointments by other physicians that is up to me but Dr. Donovan will not be able to properly advise me on the care of my scalp and use or oral minoxidil without seeing me.

INITIAL

SIGNATURE OF PATIENT

PRINTED NAME OF PATIENT

DATE (DAY-MONTH-YEAR)

I hereby attest that I have provided the above patient with all the information relevant to make informed consent about the use of minoxidil. I have answered all questions that were posed to me. I believe this patient is a good candidate for this medication.

SIGNATURE OF DOCTOR

PRINTED NAME OF DOCTOR

DATE (DAY-MONTH-YEAR)