

# Bernstein Medical

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## Consent for the Off-Label Use of Oral Minoxidil

Minoxidil is an oral medication that was initially FDA-approved in the 1970s to treat severe and treatment-resistant hypertension (high blood pressure). Doses used for the treatment of hypertension generally range between 10mg and 40mg daily. At this dose, patients who were taking minoxidil for blood pressure control were noted to have “hypertrichosis” or increased hair growth as a side effect. Minoxidil works to increase hair growth by causing a shortening of the telogen (resting) phase and lengthening of the anagen (growth) phase of the hair cycle, which increases the hair follicle diameter and length.

Topical versions of minoxidil (brand name: Rogaine) have been used for decades to help slow genetic thinning, but daily compliance with the application is a barrier to continued use and benefit. More recently, low doses of oral minoxidil have been used “off-label” to help patients with androgenetic alopecia who prefer daily oral administration over topical application. The oral form may be more effective, but this has not yet been proven in controlled studies.

Early studies have shown that oral minoxidil can be an effective treatment for male and female patients with androgenetic alopecia. Minoxidil doses used for hair loss are lower than those used previously to treat hypertension. Most patients will tolerate the medication without major side effects.

For genetic thinning in women, minoxidil in doses of 0.625mg and 1.25mg seem to be effective and safe. In addition, combination with 25mg spironolactone may increase the effectiveness and limit side effects by reducing fluid retention that can be seen with minoxidil. In men, genetic thinning is often treated with 2.5mg or 5mg of oral minoxidil daily. Spironolactone is contraindicated in men. Women who are pregnant, or are planning to get pregnant, should not take minoxidil or spironolactone.

The most common side effect experienced with low-dose oral minoxidil is hypertrichosis (excess hair around the face and/or body). This hypertrichosis is often mild and manageable in most patients. Other less common side effects include low blood pressure (that can result in dizziness), fluid retention (that would cause ankle swelling or weight gain), and EKG changes (that might be felt as palpitations i.e., irregular heart beats).

Shedding may be noted during the first few months after starting therapy. It is important not to discontinue the medication for this reason. The benefits of minoxidil will stop if the medication is discontinued. Over the two to six months following stopping, the hair loss pattern will generally return to the state that it would have been reached if the medication had never been used. You

are encouraged to return to our office for follow-up evaluations. If you experience any problems or adverse reactions while taking minoxidil, please contact us.

**It is important that you read the manufacturer’s Patient Information that comes with your medication.**

I acknowledge that the doctor has discussed with me the off-label use, and potential side effects of oral minoxidil during my office visit and that all my questions have been answered.

I acknowledge receipt of this minoxidil information sheet.

Please print:

\_\_\_\_\_

Last Name

\_\_\_\_\_

First Name

\_\_\_\_\_

Signature

\_\_\_\_\_

Date