

**【薬品構成】**

有効主成分: ミノキシジル5mg

服 用 量: 医師の指示に従ってください。(1日1回1錠)

保 管: 室温30℃以下の場所で保存してください。

**【効能】**

ミノキシジルは男性のAGA(男性型脱毛症)を治療するための経口治療薬です。この製品はミノキシジル 5mg を含有する医薬品になります。ミノキシジルの主な効能は男性の脱毛症を抑制させ、発毛を促すものです。

**【投与量】**

ミノキシジルは1日1回1錠毎日服用します。服用後3か月ほどで徐々に脱毛が改善されてきます。

※通常6か月以上の連続投与が必要。

**【注意事項】**

- ・円形脱毛症や皮膚疾患での脱毛または抗がん剤治療による脱毛には効果がありません。
- ・服用を止めてしまうと再び脱毛が進行します。
- ・20 歳以下の方は、ミノキシジルを服用しないでください
- ・毎日一定の時間に服用すること。
- ・服用開始に初期脱毛が起こることがあります。

**【ミノキシジル服用中の献血】**

ミノキシジルを服用している場合献血は避けましょう。

**【副作用の可能性】**

- ・低血圧
- ・不整脈、動悸
- ・多毛症
- ・性欲減退

※身体に異常表れた場合には服用を中止し医療機関に相談すること。

**【薬物相互作用】**

降圧剤を服用している場合過度に血圧低下を招く危険性があります。

**【過剰摂取】**

1 日あたり 2 錠以上服用しても効果は変わりません。

※血圧に悪影響を及ぼす危険性があります。

**【保管方法】**

湿気、日光をさけ、子供やペットの届かないところに置き、常温で保管してください。

**【Composition】**

Minoxidil tablets for oral administration contain either 2.5 mg or 10 mg of minoxidil. Minoxidil Tablets USP 2.5 mg and 10 mg contain the following inactive ingredients: anhydrous lactose, docusate sodium, magnesium stearate, microcrystalline cellulose, sodium benzoate and sodium starch glycolate.

**【Description】**

Minoxidil tablets contain minoxidil, an antihypertensive peripheral vasodilator. Minoxidil occurs as a white to off-white, crystalline powder, soluble in alcohol and propylene glycol; sparingly soluble in methanol; slightly soluble in water; practically insoluble in chloroform, acetone and ethyl acetate. The chemical name for minoxidil is 2,4-Pyrimidinediamine, 6-(1-piperidinyl)-, 3-oxide. The structural formula is represented below:

**【Indications】**

Because of the potential for serious adverse effects, minoxidil tablets are indicated only in the treatment of hypertension that is symptomatic or associated with target organ damage and is not manageable with maximum therapeutic doses of a diuretic plus two other antihypertensive drugs. At the present time use in milder degrees of hypertension is not recommended because the benefit-risk relationship in such patients has not been defined. Minoxidil reduced supine diastolic blood pressure by 20 mm Hg or to 90 mm Hg or less in approximately 75% of patients, most of whom had hypertension that could not be controlled by other drugs.

**【Contraindications】**

Minoxidil tablets are contraindicated in pheochromocytoma, because it may stimulate secretion of catecholamines from the tumour through its antihypertensive action. Minoxidil tablets are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

**【Side effect】**

Side effects of oral minoxidil may include swelling of the face and extremities, rapid and irregular heartbeat, lightheadedness, cardiac lesions, and focal necrosis of the papillary muscle and subendocardial areas of the left ventricle. There have been cases of allergic reactions to minoxidil or the non-active ingredient propylene glycol, which is found in some topical minoxidil formulations. Pseudoacromegaly is an extremely rare side effect reported with large doses of oral minoxidil. Minoxidil is generally well tolerated, but common side effects include burning or irritation of the eye, itching, redness or irritation at the treated area, as well as unwanted hair growth elsewhere on the body. Exacerbation of hair loss/alopecia has been reported. Severe allergic reactions may include rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue, chest pain, dizziness, fainting, tachycardia, headache, sudden and unexplained weight gain, or swelling of the hands and feet. Temporary hair loss is a common side effect of minoxidil treatment. Manufacturers note that minoxidil-induced hair loss is a common side effect and describe the process as "shedding". Alcohol and propylene glycol present in some topical preparations may dry the scalp, resulting in dandruff and contact dermatitis.

**【Dosage and Administration】**

Patients over 12 years of age: The recommended initial dosage of minoxidil tablets is 5 mg of minoxidil given as a single daily dose. Daily dosage can be increased to 10, 20 and then to 40 mg in single or divided doses if required for optimum blood pressure control. The effective dosage range is usually 10 to 40 mg per day. The maximum recommended dosage is 100 mg per day. Patients under 12 years of age: The initial dosage is 0.2 mg/kg minoxidil as a single daily dose. The dosage may be increased in 50 to 100% increments until optimum blood pressure control is achieved. The effective dosage range is usually 0.25 mg to 1 mg/kg/day. The maximum recommended dosage is 50 mg daily. Dose frequency: The magnitude of within-day fluctuation of arterial pressure during therapy with minoxidil is directly proportional to the extent of pressure reduction. If supine diastolic pressure has been reduced less than 30 mm Hg, the drug need be administered only once a day; if supine diastolic pressure has been reduced more than 30 mm Hg, and the daily dosage should be divided into two equal parts. Frequency of dosage adjustment: Dosage must be titrated carefully according to individual response. Intervals between dosage adjustments normally should be at least 3 days since the full response to a given dose is not obtained for at least that amount of time. Where a more rapid management of hypertension is required, dose adjustments can be made every 6 hours if the patient is carefully monitored.

**【Presentation】**

Minoxidil Tablets 5 mg are 9/32", scored, round, white tablets supplied in packaging of 100 tablets, with 50 tablets per strip.

※ Store at a temperature below 30°C. Protect from light and moisture.

※ Keep out of the reach of children