PRESCRIBING INFORMATION



R

COMPOSITION:

Minoxin Solution (2 %): Each ml contains: Minoxidil USP..... 20 mg Alcohol USP 0.3 g

Minoxin Plus Solution (5 %): Each ml contains: Minoxidil USP..... 50 mg Alcohol USP..... 0.3 g **مينـوڪسِٽ** ڻوييکل سلوشن

PROPERTIES

PROPERTIES: Minoxin (Minoxidil Topical Solution USP) stimulates hair growth in individuals with androgenetic alopecia expressed as baldness of the vertex of the scalp in males and in females as diffuse hair loss or thinning of frontoparietal areas. Clinical results suggest a minimum use of four months before hair growth can be expected. Topical application of Minoxidil showed no systemic effect in the prescribed dosage i.e. 2 (two) applications per day.

PHARMACOKINETICS

PHARMACOKINETICS: On topical application minoxidil is poorly absorbed, from normal intact scalp with an average of 1.4 % (0.3 to 4.5 %) of the total applied dose, reaching systemic circulation. Therefore, 1 (one) ml of Minoxidil 2 % delivering 20 mg Minoxidil and Minoxidil 5 % delivering 50 mg Minoxidil to the skin, would result in absorption of approximately 0.280 mg of Minoxidil 2 % and 0.700 mg of Minoxidil 5% respectively. Local abrasion or dermatitis may enhance absorption rate. Following cessation of topical dosing approximately 95% of systemically absorbed Minoxidil is eliminated within 4 days. Metabolic biotransformation of Minoxidi becabed deflawing topical application hose not hoon fully determined. Minoxidil absorbed following topical application has not been fully determined.

INDICATIONS AND USAGE:

INDICATIONS AND USAGE: Minoxin (Minoxidil Topical Solution USP) is indicated for treatment of androgenetic alopecia, expressed in males as baldness of the vertex of the scalp and in females as diffuse hair loss or thinning of frontoparietal area. At least, 4 (four) months of twice daily application of Minoxin (Minoxidil Topical Solution USP) are generally required before evidence of hair growth can be expected.

CONTRA-INDICATION

CONTRA-INDICATION: MINOXIA (MINOXIAL TOTAL SOLUTION USP) is contra-indicated in those patients with a history of hypersensitivity to any component of the preparation.

PRECAUTIONS AND WARNINGS:

PRECAUTIONS AND WARNINGS: Although the following effects have not been associated with the topical use of Minoxidil solution there is some absorption (on average 1.4 %) from the scalp. The potential exists for systemic effects such as tachycardia, angina, oedema and potentiation of orthostatic hypotension produced by guanethidine. Patients should be observed periodically for any such systemic effects. In the event of systemic side-effect or severe dermatologic reaction discontinue administration of the devent. of the drug.

Minoxin (Minoxidil Topical Solution USP) will cause burning and irritation to the eye. In the event of accidental contact with sensitive surface (eye, abraded skin, mucous membranes), the area should be bathed with copious amounts of cool tap water. Minoxin (Minoxidil Topical Solution USP) should not be used in conjunction with other topical agents including corticosteroids, retinoids and petrolatum or agents that are known to enhance cutaneous drug absorption.

USE DURING PREGNANCY AND LACTATION: Minoxin (Minoxidil Topical Solution USP) like other drugs should not be used by pregnant and nursing

Safety and effectiveness of Minoxidil Topical Solution in patients under 18 years of age have not been established.

INTERACTIONS: There are currently no known interactions associated with the use of Minoxidil Topical Solution. OVERDOSAGE AND ACCIDENTAL INGESTION: Accidental ingestion may produce systemic effects related to the vasodilatory action of Minoxidil. Signs and symptoms of drug overdosage would most likely be cardiovascular effects associated with fluid retention, lowered blood pressure and tachycardia. Fluid retention can be managed with appropriate diuretic therapy. Tachycardia can be controlled by administration of a beta adrenergic blocking agent. Hypotension should be treated by intravenous administration of normal saline. Sympathomimetic drugs, such as norepinephrine and epinephrine should be avoided because of their excessive cardiac stimulating activity. DOSAGE AND ADMINISTRATION: DOSAGE AND ADMINISTRATION: For external use only. Use Minoxin only as directed. Do not apply to any other area of the body. A total dose of 1 ml Minoxin should be applied twice daily on the scalp, beginning at the center of the affected area. This dose should be used regardless of the size of the affected area. Six pumps of the applicator release approx. 1 ml of Minoxin. The total daily dose should not exceed 2 ml. To avoid any systemic absorption, wash hands thoroughly after applying Minoxin. Apply Minoxin when the hair and scalp are thoroughly dried. Don't use a hairdryer to speed the drying of Minoxin solution because blowing air on the scalp may decrease the effectiveness of Minoxin solution because blowing air on the scalp may decrease the effectiveness of Minoxin. STORAGE Keep all medicines out of reach of children. Store at temperature 15 to 30°C away from light. PRESENTATION: مقداراورطريقهاستعال: Minoxin Solution (2%): Bottle of 60 ml with applicator. Minoxin Plus Solution (5%): Bottle of 60 ml with applicator. صرف بیرونی استعال کے لیئے: منوکسِن صرف دی گئی ہدایات کے مطابق استعال کریں ۔جسم کے کنی دوسرے حصر پراستعال نہ کریں۔ منوکسِن کی مقدار 1ml سر پر دومرتبہ میں اورشام استعال کریں۔ اس کا استعال سرے متاثرہ جگدے مرکز ہے شروع کریں۔ یہ مقدار متاثرہ جگدے سائز پر مخصر نہیں۔ منوکسن ٹو پیکل سلوثن کو چھ دفعہ اسیرے کرنے ہے دوا کی مقدار تقریباً 1ml تک نگلتی ہے۔ یومیہ مقدارا ستعال 2ml سے زیادہ نہیں ہونی چاہیے۔ منوکسِن ٹو پیکل سلوٹن کے استعال کے بعد ہاتھوں کو فوراً اچھی طرح دھولیں تا کہ دواجذب نہ ہو سکھ ۔ منوکسِن کے استعال سے پہلےا س بات کا اطمینان کرلیں کہ آئے بال کمل طور پر خشک ہوں یہ منوکس کے استعال کے بعد دواکوخشک کرنے کیلئے ہیئر ڈرائیر ہرگز استعال نہ بچینے بہیئر ڈرائیر کا کااستعال دوائے اثر کوکم کرسکتا ہے۔ اسٹوری: تمام دوائیں بچوں کی پنچ سے دورر کھیئے۔ 15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر دوشنی سے بچا کرر کھیئے۔ Grookes Manufactured by: Brookes Pharma Private Limited 58 - 59 Sector 15 Korangi Industrial Area Karachi 74900 Pakistan.