COMPOSITION:
Minoxidil Topical Solution USP contains:
- Minoxidil USP 20 mg
- Alcohol USP 0.3 g

PROPERTIES:
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:
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. Serum Minoxidil levels resulting from topical administration are governed by the drug's percutaneous absorption rate. Following cessation of topical dosing approximately 95% of systemically absorbed Minoxidil is eliminated within 4 days. Metabolic biotransformation of Minoxidil absorbed following topical application has not been fully determined.

INDICATIONS AND USAGE:
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 Minoxidil Topical Solution USP are generally required before evidence of hair growth can be expected.

CONTRA-INDICATION:
Minoxidil Topical Solution USP is contra-indicated in those patients with a history of hypersensitivity to any component of the preparation.

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 drug.

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. 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:
Minoxidil Topical Solution USP like other drugs should not be used by pregnant and nursing women.

PAEDIATRIC USE:
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.

OVERDOSE 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.

DOSE 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.

STORAGE:
Keep all medicines out of reach of children.
Store at temperature 15 to 30°C away from light.

PRESENTATION:
Minoxin Solution (2%): Bottle of 60 ml with applicator.
Minoxin Plus Solution (5%): Bottle of 60 ml with applicator.

Manufactured by:
Brookes Pharma Private Limited
5-8, 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan.