MINOX 5%
TOPICAL SOLUTION
(Extra Strength)

MAL16025045AZ

COMPOSITION:
Minoxidil 3.0g / 60ml

PRESENTATION:
Colourless to mild golden colour liquid.

INDICATIONS:
Minox 5% Topical Solution (Extra Strength) is exclusively indicated for the treatment of alopecia androgenetica (hereditary hair loss) in males & female. Minox 5% Topical Solution (Extra Strength) prevents further hair loss and regrows hair in patients with alopecia androgenetica.

PHARMACOLOGY:
Mechanism of Action:
When applied topically, minoxidil has been shown to stimulate hair growth in individuals with alopecia androgenetica. The onset of hair growth stimulation occurs approximately after 4 or more months of use and is variable among patients. Upon discontinuation of minoxidil, new hair growth stops and restoration of pre-treatment appearance is expected within 3-4 months. The exact mechanism of action of minoxidil in the treatment of alopecia androgenetica is not known. Topical application of minoxidil showed no systemic effects related to absorption of minoxidil, when tested in controlled clinical trials in both normotensive and untreated hypertensive patients. In the treatment of hypertension, orally administered minoxidil has a direct peripheral vasodilator effect that reduces elevated systolic and diastolic blood pressure decreasing peripheral vascular resistance. Reduction of peripheral arteriolar resistance and the associated fall in blood pressure trigger sympathetic, vagal inhibitory and renal homeostatic mechanisms, including an increase in renin secretion, that lead to increased cardiac rate and output and salt and water retention. Minoxidil does not interfere with vasomotor reflexes and therefore does not produce orthostatic hypotension. In experimental animals the drug does not enter the central nervous system in significant amounts. Minoxidil does not affect CNS function in man.

Pharmacokinetics:
Following the topical application of minoxidil, it is poorly absorbed from normal intact skin, with an average of 1.4% (range 0.3 - 4.5%) of the total applied dose ultimately reaching the systemic circulation. Therefore a 1ml dose of minoxidil 5%, delivering 50mg minoxidil to the skin, would result in absorption of approximately 0.7mg minoxidil. The effects of concomitant dermal diseases on absorption are unknown. Serum minoxidil levels resulting from topical administration of minoxidil are governed by the drug's percutaneous absorption rate. Following the cessation of topical dosing minoxidil, approximately 95% of systemically absorbed minoxidil is eliminated within 4 days. The metabolic biotransformation of minoxidil absorbed following topical application of minoxidil has not been fully determined. Minoxidil is almost completely absorbed from the gastro-intestinal tract following oral administration of minoxidil tablets. It is metabolized predominantly by conjugation with glucuronic acid at the N-oxide position in the pyrimidine ring but also by conversion to more polar products. Known metabolites exert much less pharmacologic effect than minoxidil itself. Minoxidil does not bind to plasma proteins and its renal clearance corresponds to the glomerular filtration rate. Minoxidil does not cross the blood brain barrier. Minoxidil and its metabolites are hemodialyzable and are excreted principally in the urine.

ROUTE OF ADMINISTRATION:
For external use only. Use Minox 5% Topical Solution (Extra Strength) as directed. Do not apply Minox 5% Topical Solution (Extra Strength) to any other area of the body.

DIRECTION FOR USE:
For adult (aged between 18 - 65 years), a total dose of 1ml (equivalent to 10 sprays) of Minox 5% Topical Solution (Extra Strength) should be applied twice per day to the scalp, beginning at the center of the affected area. This dose should be used regardless of the size of the affected area. Avoid breathing spray mist. The total daily dose should not exceed 2ml (equivalent to 20 sprays). Shake the container well before each use. Apply Minox 5% Topical Solution (Extra Strength) when the hair and scalp are thoroughly dry. After applying, wash hands thoroughly. The method of application varies according to the disposable applicator used, as indicated below:

Pump Spray Applicator :
1. This applicator works best for applying Minox 5% Topical Solution (Extra Strength) to large areas of the scalp.
2. Remove the outer cap from the spray head.
3. After aiming the spray head toward the center of the bald area of the scalp, press once and spread Minox 5% Topical Solution (Extra Strength) with fingertips to cover all of the bald area. Repeat for a total of 10 times to apply a dose of 1 ml of solution. Leave it dry after application. Do not rinse. Avoid breathing spray mist. Place the outer cap back to the spray head when not in use.

Extended Spray-Tip Applicator :
1. This applicator works best for applying Minox 5% Topical Solution (Extra Strength) to small areas of the scalp or under hair.
2. Remove outer cap together with the spray head; fit the extended spray tip applicator onto the spray shaft and push down firmly.
3. After aiming the extended spray-tip applicator toward the center of the bald area of the scalp, press once and spread Minox 5% Topical Solution (Extra Strength) with fingertips to cover all of the bald area. Repeat for a total of 10 times, to apply a dose of 1 ml of solution. Leave it dry after application. Do not rinse. Avoid breathing spray mist.

It may take twice daily applications for 4 months or more before evidence of hair growth can be expected. Onset and degree may be variable among patients.

CONTRAINDICATION:
Contraindicated in those patients with a history of hypersensitivity to any ingredients of Minox 5% Topical Solution (Extra Strength).

PRECAUTION:
Before using Minox 5% Topical Solution (Extra Strength), the physician should determine that the patient has a normal scalp. Minoxidil is only indicated for the treatment of alopecia androgenetica and should not be used in other types of hair loss for example when there is no family history of hair loss, hair loss is sudden and/ or patchy, hair loss is due to childbirth or the reason for hair loss is unknown. Patients should stop using Minox 5% Topical Solution (Extra Strength) and consult doctor if hypotension is detected of the patient is experiencing chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness. Minox 5% Topical Solution (Extra Strength) may cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin mucous membranes), the area should be bathed with copious amount of cool tap water. Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of reach of children. Safety and effectiveness of minoxidil solution in users aged under 18 or over 65 has not been established.

Use in Pregnancy and Lactation:
There are no adequate and well-controlled studies in pregnant women. Systemically absorbed minoxidil is secreted in human milk. Minox 5% Topical Solution (Extra Strength) should not be used during pregnancy or lactation.

SIDE EFFECTS:
The most encountered adverse effect was mild dermatitis of the scalp. Infrequently reported adverse effects included irritant dermatitis (redness, scaling and burning), dry skin, nonspecific allergic reactions, hives, allergic rhinitis, facial swelling, sensitivity, shortness of breath headache, neuritis, dizziness, lightheadedness, syncope, vertigo, edema, chest pain, blood pressure changes, palpitations and pulse rate changes.

DRUG INTERACTION:
Topical drugs, such as corticosteroids, tretinoin, dithranol or petroleum, which alter the stratum corneum barrier, could result in increased absorption of minoxidil if applied concurrently. Although it has not been demonstrated clinically, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

OVERDOSAGE AND TREATMENT:
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 β-adrenergic blocking agent. Symptomatic 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.

STORAGE:
Store below 30^{o}C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

Shake container well before each use.

PACK QUANTITIES:
Available in glass bottle of 60ml.

Further information can be obtained from doctor, pharmacist or the manufacturer.

Manufactured By & Product Registration Holder :
KOTRA PHARMA
Kotra Pharma (M) Sdn. Bhd. (90082-V)
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Cheng Industrial Estate,
75250 Melaka, Malaysia.

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