ANDROANAGEN SOLUTION

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ANDROANAGEN SOLUTION (Minoxidil Topical Solution USP 5.0% w/v)

[Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: When applied topically, it has been shown to stimulate hair growth in individual male pattern baldness and hair loss occurring on the crown of the scalp. The mechanism is not fully understood, but minoxidil can reverse the hair loss process by the means: Increase the diameter of the hair shaft, Stimulate anagen growth, Prolong the anagen phase, Stimulate anagen recovery from the telogen phase as a peripheral vasodilator minoxidil enhances microcirculation to hair follicles. The Vascular Endothelial Growth Factor (VEGF) is stimulated by minoxidil and VEGF is presumably responsible for the increased capillary fenestration, indicative of a high metabolic activity, observed during the anagen phase.

INDICATIONS: ANDROANAGEN SOLUTION is indicated for the treatment of alopecia (male pattern baldness) in men.

DOSAGE AND ADMINISTRATION: *Dosage form*: Metered Dose Spray, *Dosage Strength*: Minoxidil I.P. 5.0% w/v.

CONTRAINDICATION: ANROANAGEN SOLUTION is contraindicated in the following situations: Patients with hypersensitivity to any of the ingredients of the formulation, Children below 18 years of age, pregnant women or nursing mothers, Hair loss of unknown reasons, Patients with occlusive dressings or other medicines on the scalp, On a shaved scalp, or if there is no family history of hair loss, there is sudden and/or patchy hair loss, Patients with red, inflamed infection, or irritated or painful scalp (including psoriasis and sunburn), Patients with hypovolemic states (Ex-co-treatment with diuretics, dehydration etc.), Patients with hypertension, including those under treatment with antihypertensive agents, should be monitored closely and their medication adjusted if necessary, ANDROANAGEN SOLUTION should be used with caution in patients with any other cardiovascular disease.

WARNINGS & PRECAUTIONS: Although the following systemic effects have not been associated with the use of Minoxidil. Solution, there is some absorption of Minoxidil from the skin and the potential exists for systemic effects such as Tachycardia, Angina, and Edema. Patients should be monitored periodically for any systemic effects of Minoxidil. In the event of systemic effects, discontinue the use. In case of accidental contact with sensitive surfaces (such as Eyes, abraded skin and Mucous Membranes), the area should be rinsed with large amounts of cool tap water. It is ideal and beneficial to wash the scalp with a gentle Hair Cleanser before applying ANDROANAGEN SOLUTION.• Hair sprays or styling products may be used on the hair while using Minoxidil Solution but for best results, it should be allowed to penetrate into the scalp before using any styling products.

DRUG INTERACTIONS: Currently, there are no known drug interactions associated with the use of Minoxidil Solution. There exists the possibility of potentiating Orthostatic Hypotension in patients currently taking Guanethidine, although it has not been clinically demonstrated.

ADVERSE REACTIONS: Local irritation: Erythema/flushing, dry skin, itching, burning sensation and rash. Dermatitis or Hypertrichosis may occur allergic reaction, Dizziness, Headache, tingling sensation, weakness, Oedema, eye irritation, otitis externa, visual disturbance, hair abnormalities, chest pain, alterations in pulse or Blood Pressure and Hepatitis.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)