PACKAGE INSERT

MINOXIDIL LOTION 3% W/V

Containing:
Minoxidil 3% w/v

Product Description: A clear, colourless lotion.

Pharmacodynamics:
When applied topically, minoxidil has been shown to stimulate hair growth and prevent hair loss in male pattern baldness and alopecia areata. The onset of hair growth stimulation 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 male pattern baldness is not known. Topical application showed no systemic effects related to absorption of minoxidil.

Pharmacokinetics:
Following topical application, minoxidil is poorly absorbed from normal intact skin. The effects of concomitant dermal diseases or occlusion on minoxidil absorption are unknown. Serum minoxidil levels resulting from topical administration are governed by the drug's percutaneous absorption rate. Following cessation of topical dosing of minoxidil, approximately 95% of systemically absorbed minoxidil is eliminated within 4 days. The metabolic biotransformation of minoxidil absorbed following topical application has not been fully dertermined.

Indication:
Alopecia androgenetica.

Recommended Dosage:
For external use only. Use only as directed. Do not apply to any other area of the body. A total dose of 1ml should be applied twice/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. The total daily dose should not exceed 2 ml. After application wash hands thoroughly. Apply when the hair and scalp are thoroughly dry.

The method of application varies according to the disposable applicator used, as follows:
1) Remove outer cap.
2) Aim the pump toward the center of the bald area of the scalp.
3) Press the pump once and spread lotion with fingertips to cover all of the bald area.
4) Repeat for a total of 8 times, to apply a dose of 1ml of lotion. Avoid breathing spray mist.
5) Place outer cap on bottle when not in use.

Route of Administration: Topical

Contraindications:
Patients with a history of hypersensitivity to minoxidil. Contraindicated in phaechromocytoma.

Warnings and Precautions:
Minoxidil may be absorbed through the skin and the potential exists for systemic effects, such as tachycardia, angina, edema or potentiation of the orthostatic hypotension produced by guanethidine. Patients should be observed periodically for any signs of systemic effects of minoxidil. Discontinue administration of the drug in the event of systemic side effects. Minoxidil Lotion 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 amounts of cool tap water.

Interactions with other Medicaments:
There are currently no known drug interactions associated with the topical use of minoxidil. Although it has not been clinically demonstrated, there exists the possibility of potentiating orthostatic hypotension in patients concurrently taking guanethidine.

Pregnancy and Lactation:
The effects of Minoxidil Lotion in pregnancy are unknown. Systemically absorbed minoxidil is excreted in human milk. Minoxidil Lotion should not be used by pregnant or nursing women.

Side Effects:
The most frequently encountered adverse reactions are minor dermatologic reactions. Local irritation was the most common adverse reaction reported, including scaling, erythema/flushing, dermatitis, dry skin, burning sensation and rash. Infrequently reported adverse reactions include allergic reactions; dizziness; tingling sensation; headache; weakness; neuritis; edema; eye irritation; altered taste; ear infection and visual disturbances.

Symptoms and Treatment of Overdose:
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. Hypotension should be treated by IV administration of normal saline. Sympathomimetic drugs, eg norepinephrine and epinephrine, should be avoided because of their excessive cardiac-stimulating activity.

Effects on Ability to Drive and Use Machine: Not applicable.

Storage Conditions: Store at below 30°C.

Pack Sizes: A bottle of 30ml and 60ml.

Shelf-life: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
No. 9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

EL214A-R2
Revision Date: 31/12/2025