AVOXIDIL Topical Solution 5 % w/v

Composition

Each ml contains:

Minoxidil	50 mg

PRODUCT DESCRIPTION

A colorless to light yellowish clear liquid.

INDICATION

Avoxidil Topical Solution 50mg/ml spray is exclusively indicated for the treatment of alopecia androgenetica in males and females. Avoxidil Topical Solution 50mg/ml spray stimulates hair growth and stabilizes hair loss in patients with alopecia androgenetica.

PHARMACOLOGICAL PROPERTIES

ATC code: D11AX01

Pharmacotherapeutic group: Dermatological preparations containing minoxidil

Pharmacodynamic properties

Mechanism of action:

The exact mechanism of action of minoxidil in the treatment of alopecia androgenetica is not known. However, 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 Avoxidil Topical Solution 50mg/ml, new hair growth stops and restoration of pretreatment appearance is expected within 3 -4 months.

Pharmacokinetic properties

Following topical application, minoxidil 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 1 mL dose of Avoxidil Topical Solution 50mg/ml, delivering 50 mg minoxidil to the skin, would result in absorption of approximately 0.70 mg 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 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 determined.

RECOMMENDED DOSAGE

Route of administration: For external use only.

Use Avoxidil only as directed. Do not apply Avoxidil to any other area of the body.

A total dose of 1 mL Avoxidil 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. The total daily dose should not exceed 2 mL.

Apply Avoxidil when the hair and scalp are thoroughly dry. When in use, avoid inhalation of spray mist. After applying Avoxidil wash hands thoroughly.

Using the Spray applicator

The method of application varies according to the disposable applicator used, as indicated below.

A. PUMP SPRAY APPLICATOR: This applicator works best for applying Avoxidil to large areas of the scalp.

B. EXTENDED SPRAY-TIP APPLICATOR: This applicator works best for applying Avoxidil to small areas of the scalp and under hair.

Instructions of pump spray applicator:

1. Remove large outer cap; remove small inner cap and discard it.
2. Insert the pump spray applicator into bottle and screw on firmly.
3. After aiming the pump toward the center of the bald area of the scalp, press the pump once and spread Avoxidil with fingertips to cover all of the bald area.
4. Repeat for a total of 7 times, to apply a dose of 1 mL of solution.
5. Place large outer cap on bottle when not in use.

CONTRAINDICATIONS

Avoxidil is contraindicated in those patients with a history of hypersensitivity to minoxidil or any of the other ingredients.

WARNING AND PRECAUTIONS

Patients being considered for minoxidil therapy should have a history and physical examination taken. The physician should determine that the patient has a normal scalp.

There is no evidence that enough minoxidil is absorbed to cause systemic effects, some absorption of minoxidil from the skin does occur and the potential exists for systemic effects such as salt and water retention, generalized and local edema, pericardial effusion, pericarditis, tamponade, tachycardia, angina or potentiation of the orthostatic hypotension produced by guanethidine.

Patients with a history of underlying heart diseases should be made aware that minoxidil may aggravate these conditions. Patients should be observed periodically for any suggestion of systemic effects of minoxidil.

In the event of systemic side effects discontinue administration of the drug. If necessary, fluid retention and edema can be managed with diuretic treatment. Tachycardia and angina can be controlled by administration of β-adrenergic blocking drugs or other sympathetic nervous system suppressants. Patients should discontinue use of Avoxidil and contact their physician in the event of systemic effects or severe dermatologic reactions.

Minoxidil 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.

Accidental ingestion of minoxidil could lead to serious side effects.

Inform your patients to keep this and all medications out of the reach of children.

The effects of minoxidil in patients with concomitant dermal diseases or in those using topical corticosteroids or other dermatologic preparations are unknown.

Pediatric Use

Safety and effectiveness in patients below the age of 18 years have not been established.

DRUG INTERACTIONS

There are currently no known drug interactions associated with the use of minoxidil. However, there exists the possibility of potentiating orthostatic hypotension in patients concurrently taking peripheral vasodilators.

PREGNANCY & LACTATION

The effects of Avoxidil in pregnancy are unknown.

Nursing Mothers

Systemically absorbed minoxidil is secreted in human milk. Hence, Avoxidil should not be used by pregnant or nursing mothers.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.

SIDE EFFECTS

The most frequently encountered side effect with topical application of minoxidil was mild dermatitis of the scalp.

Infrequently reported side effects included irritant dermatitis (redness, scaling and burning), 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.

Rarely reported side effects included allergic contact dermatitis, folliculitis, alopecia (hair loss), unwanted hypertrichosis and seborrhea.

Other than mild dermatological events, a causal relationship between the above mentioned side effects and the use of minoxidil has not been established.

SIGNS AND SYMPTOMS 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.

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°C. Protect from light and moisture.
Keep in a tightly closed container, protect from light. Keep out of reach of children.

PACKING:
60ml in white HDPE bottle with white PP cap (with PE foam gasket) and packed in a printed box with a package insert and white spray applicator.

Product Registration holder:
Abio Marketing Sdn Bhd
No. 2, Jalan SS 13/5, 47500 Subang Jaya, Selangor, Malaysia

Manufactured by
Sinphar Pharmaceutical Co. Ltd. (Taiwan),
No. 84, Chung Shan Village, Tung-Shan Shine, Yei-Lan, Taiwan R.O.C..

Malaysia Registration No. MAL20076046ACZ

Revision date: March 2022