ASU MINOXIDIL Topical Solution 5% w/v

Composition

Each ml contains:

Minoxidil	50 mg

PRODUCT DESCRIPTION
A colorless to pale yellow transparent liquid with alcoholic smell.

INDICATION
Asu Minoxidil Topical Solution 5% w/v is exclusively indicated for the treatment of alopecia androgenetica in males and females. Asu Minoxidil Topical Solution 5% w/v 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
The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by increasing the diameter of the hair shaft, stimulating anagen growth, prolonging the anagen phase and stimulating anagen recovery from the telegon 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.

Pharmacokinetic properties

About 0.3 to 4.5% of a topical dose of minoxidil is absorbed from intact scalp. Minoxidil is not bound to plasma proteins. It is distributed into breast milk. Minoxidil is extensively metabolised by the liver. It requires sulfation to become active, but the major metabolite is a glucuronide conjugate. Minoxidil is excreted predominantly in the urine mainly in the form of metabolites. Minoxidil and its metabolites are dialysable, although the pharmacological effect is not reversed.

RECOMMENDED DOSAGE

Route of administration: For external use only.

Use Asu Minoxidil Topical Solution 5%w/v only as directed. Do not apply Asu Minoxidil Topical Solution 5%w/v to any other area of the body.

A total dose of 1 mL Asu Minoxidil Topical Solution 5%w/v 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. 1 drop equal to 1/6ml of the product.

Apply Asu Minoxidil Topical Solution 5%w/v when the hair and scalp are thoroughly dry. After applying Asu Minoxidil Topical Solution 5%w/v wash hands thoroughly.

Method of Administration

Using the Dropper
1. Open the external cap, turn the internal cap and discard it.
2. Pipette the solution into the dropper to 1ml, apply slowly, evenly to the bad area and massage the area with fingers. A total of 6 times will deliver standard amount of 1ml.
3. To keep the durability of the dropper, do not face the mouth of dropper upward when applying.
4. When finish applying, place the dropper in the bottle tightly and cover the external cap.

CONTRAINDICATIONS
The 5% minoxidil solution is not recommended for women.

Not to be used by those who are known hypersensitivity to Minoxidil.

Should not be applied to inflamed scalp skin or areas affected by psoriasis, severe sunburn, or severe excoriations, because of the risk of increased absorption

WARNING AND PRECAUTIONS

Topical Minoxidil is only indicated for the treatment of alopecia androgenetica and should not be used in other type 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. Topical application of minoxidil should be restricted to the scalp.

Patients being treated for hypertension should be monitored if topical minoxidil is used concurrently.

Minoxidil topical solution will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded ski, mucous membranes), the area should be bathed with copious amounts of cool tap water.

Use in Children:
Safely and efficacy of minoxidil topical solution 5% in patients under 18 years of age have not been established.

Use in elderly:
Safely and efficacy of minoxidil topical solution 5% in patients over 65 years of age have not been established.

DRUG INTERACTIONS

Should not be used concomitantly with other medications applied topically on the scalp. Topical drugs, such as corticosteroids, tretinoin, dithranol or petrolatum, 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.

Effects on Ability to drive and use machines
This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery

PREGNANCY & LACTATION

This product should not be used during pregnancy and lactation.

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Studies in animal have shown a risk to the foetus at exposure levels that are very high compared to those intended for human exposure.

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

SIDE EFFECTS
Topical application of minoxidil may be associated with contact dermatitis, pruritus, local burning, and flushing; sufficient may be absorbed to produce systemic adverse effects. Changes in hair color texture may occur.

Immune system disorder
Common: Hypersensitivity reactions (including face oedema, generalized erythema, pruritus generalized, swelling face, and throat tightness).
Not known: Angioedema (including lip eodema, lip swelling, oedema mouth, oropharyngeal swelling, pharyngeal oedema, swollen tongue and tongue oedema).

Psychiatric disorders
Not known: Depressed mood.

Nervous System Disorder
Very common: Headache
Uncommon: Dizziness

Eye disorder
Not known: Eye irritation

Cardiac disorder
Common: Chest pain
Uncommon: Palpitations.
Not known: Heart rate increased.

Vascular disorders
Not known: Hypotension
Respiratory, thoracic and mediastinal disorders
Uncommon: dyspnea.

Gastrointestinal disorders
Uncommon: Nausea
Not known: Vomiting

Skin and subcutaneous disorders
Common: Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), pruritus (including rash pruritic generalized and eye pruritus), rash (including pustular, popular, generalized, vestibular and macular rash), dermatitis (including contact, allergic, atopic and seborrheic dermatitis).
Rare: Changes in hair texture
Not known: Dry skin, skin exfoliation (including rash and dermatitis exfoliate), acne (acneiform rash), temporary hair loss, changes in hair color.

General disorder and administration site conditions
Common: Oedema peripheral
Not known: Application site reactions (these sometimes involve nearby structures like the ears and face and typically consists of pruritus, irritation, pain, rash, oedema, dry skin, erythema, and rash erythematous but can sometimes be more severe and include exfoliation, dermatitis, blistering, bleeding and ulceration).

Investigations
Common: Weight increased

SIGNS AND SYMPTOMS OF OVERDOSE
Increased systemic absorption of minoxidil may potentially occur if higher than recommended doses are applied to larger surface areas of the body or areas other than the scalp.

Accidental ingestion has the potential of producing systemic effects related to the pharmacological action of the drug. Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects associated with sodium and water retention. Tachycardia, hypotension, dizziness and lethargy can also occur.

Treatment of minoxidil overdosage should be symptomatic and supportive.

Fluid retention can be managed with appropriate diuretic therapy. Clinically significant tachycardia can be controlled by administration of beta-adrenergic blocking agent.

STORAGE:

Store below 30°C.
Keep in a tightly closed container, protect from light & moisture.
Keep out of reach of children.

PACKING:

60ml in PET bottle with HDPE cap, and packed in a printed box with a dropper.

Product Registration holder:
Asumed Biotech Sdn Bhd
7-3, Subang Business Centre, Jalan USJ 9/5Q,
47620 Subang Jaya, Selangor

Manufactured by
Chen Ho Pharmaceutical Co., Ltd Sinying Plant
No. 23, Singong Road, Jiafang Vill., Sinying Dist., Tainan City, 730 Taiwan, R.O.C

Imported by
Nano Medic Care Sdn Bhd,
No. 1-16 & 1-12, 1st floor, Jalan Indah 2, Taman Indah,
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Malaysia Registration No. MAL22026004ACZ

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