Minoxidil, Tretinoin & Azelaic acid

MINOKEM N SOLUTION

1. NAME OF THE MEDICINAL PRODUCT

Minoxidil, Tretinoin & Azelaic acid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Minoxidil ……5.0%

Tretinoin.....0.01%

Azelaic acid.....1.5%

Absolute alcohol IP…….65%

3. PHARMACEUTICAL FORM

Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Minokem N is indicated for treatment of Androgenetic Alopecia in adult males.

Androgenetic Alopecia is expressed in males as baldness of the vertex of the scalp and/or as frontal hair recession.

4.2 Mode of Application:

Clean and dry the scalp area before applying the medication. Open the cap and take the right quantity of the Minokem Solution and apply on the affected scalp area with the dropper provided. Spread the solution evenly with the finger tip.

Frequency of Application:

1 ml to be applied once-daily applications for the 5% Minokem N Solution.

4.3 Contraindications

"Minokem N is contraindicated in patients with hypersensitivity to minoxidil, tretinoin and azelaic acid or ethanol.

4.4 Special Warnings and Special Precautions for Use

Before using Minokem N, tell your doctor if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. If you have any of the following health problems, consult your doctor before using this product; diseases of the scalp (e.g., eczema, infection, cuts), heart problems (e.g., chest pain, heart attack, heart failure), kidney disease, liver disease.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Drug interactions may change how the medications work or increase your risk for serious side effects. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: drugs for high blood pressure (e.g., guanethidine), drugs that interact with alcohol (e.g., disulfiram, metronidazole).

4.6 Fertility, Pregnancy and Lactation

Pregnancy

During pregnancy, this product should be used only when clearly needed. Discuss the risks and benefits with your doctor.

Nursing Mother

It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

Carcinogenicity

A 1-year study of minoxidil applied topically in rats and rabbits showed no evidence of carcinogenicity.

Mutagenicity

Minoxidil was not found to be mutagenic in the Salmonella (Ames) test, the DNA damage/alkaline elution assay, or the rat micronucleus test

Pediatrics

No information is available on the relationship of age to the effects of topical minoxidil in pediatric patients. Safety and efficacy have not been established for pediatric patients up to 18 years of age. Use in

infants is not recommended.

Geriatrics

No information is available on the relationship of age to the effects of this medication in geriatric patients. Safety and efficacy have not been established in patients older than 65 years of age. Older patients up to 65 years of age have not demonstrated geriatric-specific problems that would limit the usefulness of topical minoxidil; however, the best results are shown in younger patients with a short history of hair loss.

4.7 Undesirable Effects

Contact dermatitis.

Allergic reaction (reddened skin; skin rash; swelling of face)

Folliculitis (acne; inflammation or soreness at root of hair)

Burning, stinging, or redness at the application site may occur.

If any of these effects persist or worsen, contact your doctor promptly.Rarely, this medication can be absorbed through the skin and cause side effects. Stop using this medication and tell your doctor right away if you have any serious side effects, including: unwanted facial/body hair, dizziness, fast/irregular heartbeat, fainting, chest pain, swelling of hands/feet, unusual weight gain, tiredness, difficulty breathing especially when lying down.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

4.8 Overdose

Symptoms of overdose may include: dizziness, drowsiness, fainting, flushing.

Treatment of overdose

If systemic toxicity occurs as a result of overdose by oral ingestion of topical minoxidil, treatment may include the following :

To enhance elimination —Hemodialysis. Minoxidil and its metabolites are hemodialyzable.

Specific treatment—Hypotension may be treated with phenylephrine, angiotensin II, vasopressin, or dopamine, but these medications are recommended only if lack of perfusion of a vital organ occurs.

- Sympathomimetic medications, such as norepinephrine or epinephrine, should be avoided because of the risk of excessive cardiac stimulation.
- Supportive care—Administration of intravenous sodium chloride injection is recommended to maintain blood pressure and facilitate urine formation.
- Patients in whom intentional overdose is known or suspected should be referred for psychiatric consultation.

Proper use of this medication

- Not using more medication or more frequently than prescribed; not applying to other parts of body; risk of adverse systemic effects with excessive use
- Proper administration technique: Applying to affected area of dry scalp, beginning at the center of the balding area; not shampooing hair for 4 hours after minoxidil application
- Avoid contact with eyes, nose, or mouth; flushing area with large amounts of cool tap water if accidental contact occurs; avoiding inhalation of pump spray
- Missed dose: Using as soon as remembered if within a few hours; not using if almost time for next dose; not doubling amount used

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Topical minoxidil:

Stimulates hair growth in some persons with Androgenetic alopecia. The mechanism by which minoxidil stimulates hair growth is not established, but possible mechanisms include increased cutaneous blood

flow as a result of vasodilation, stimulation of resting hair follicles (telogen phase) into active growth (anagen phase), and stimulation of hair follicle cells.

Tretinoin:

It's a first generation topical retinoids. It binds to nuclear retinoic acid receptor.

Normalize the pattern of keratinization and promotes and regulates cell proliferation and differentiation in the epithelium and may promote vascular proliferation. Tretinoin also increases the percutaneous absorption of Minoxidil.

Azelaic acid:

Azelaic acid is a strong type I 5-alpha reductase (5-AR) inhibitor. Inhibit the production of dihydrotestosterone (DHT), prevent hair follicle damage so as the hair loss.

5.2 Pharmacokinetic Properties

Absorption:

Low percutaneous absorption; 1.6 to 3.9% of the total applied topical dose is absorbed systemically; however, absorption may increase if medication is applied to inflamed skin. Applying a 5-microliter-per-squared-centimeter dose to the entire scalp is expected to yield a systemic dose of 1.2 mg for the 1% topical solution of minoxidil and 2.7 mg for the 5% solution of minoxidil. Applying a 1 or 2% topical concentration of minoxidil to up to 50% of the scalp is unlikely to cause systemic side effects, since the average absorbed dose is less than 1.2 mg of minoxidil.

Elimination:

Renal—Approximately 95% of systemically absorbed minoxidil is eliminated within 4 days

6. PHARMACEUTICAL PARTICULARS

6.1 Shelf-life: 24 months

6.2 Special Precautions for Storage: Store below 250C protect from light

6.3 **Nature and contents of container:** 60 ml bottle

Marketed by: Alkem Labs Limited
Alkem House;
SenapatiBapat Marg,
Lower Parel; Mumbai,
Maharashtra: 400 013.