

5% Topical Solution  
**MINOXOL**  
 ( Minoxidil )

5% مینوکسولین سلوشن  
 مائینوکسول  
 (مائینوکسیدیل)

**COMPOSITION**

Each ml contains:

Minoxidil .....50mg

(USP specifications)

**DESCRIPTION**

Minoxidil Topical Solution stimulates hair growth in individuals with androgenetic alopecia expressed as baldness of the vertex of the scalp as diffuse hair loss or thinning of frontoparietal areas. Clinical results suggests a use of minimum four months before hair re growth can be expected.

Topical application of minoxidil showed no systemic effect in the prescribed dosage i.e. two applications per day.

**INDICATIONS AND USAGE**

Minoxidil topical solution is indicated for treatment of:

- Slowing of hair loss in alopecia androgenetica.
- Regrowth of hair in alopecia androgenetica.

Onset and degree of hair regrowth may be variable among users. Those users who are younger, who have been balding for a shorter period of time or who have a smaller area of baldness on the vertex are more likely to respond to minoxidil topical solution individual responses cannot be predicted.

**MECHANISM OF ACTION**

The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by the following means:

- increasing the diameter of the hair shaft
- stimulating anagen growth
- prolonging the anagen phase
- stimulating 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.

**DOSAGE & ADMINISTRATION**

Minoxidil topical solution is for adult men and women between 18 and 65 years of age.

Hair and scalp should be thoroughly dry prior to topical application of minoxidil topical solution. A dose of 1 ml of minoxidil topical solution should be applied to the total affected areas of the scalp twice daily (once in the morning and once in the evening). The total dosage should not exceed 2 ml. If fingertips are used to facilitate drug application, hands should be washed afterwards.

**Duration of use**

It may take at least 2 to 4 months of twice a day treatment before results are seen. Onset and degree of hair growth may be variable among patients. Continuous twice-daily usage is necessary to maintain the results of treatment. Relapse to pre-treatment appearance following discontinuation of medication has been reported to occur within 3-4 months. In the absence of any clear response in men, the treatment should be discontinued after 12 months (8 months in women). The method of application varies according to the disposable applicator used:

**Pump spray applicator:** This is useful for large areas. Aim the pump at the center of the bald area, press once and spread with fingertips over the entire bald area. Repeat for a total of 6 times to apply a dose of 1 ml. Avoid breathing spray mist.

**Extended spray tip applicator:** This is useful for small areas, or under hair. The pump spray applicator must be in place in order to use this additional applicator. Use in the same way as the pump spray.

The solution is flammable and exposure of the container and contents to naked flames should be avoided during use, storage and disposal. For topical use only. Do not apply to any other area of the body. The hair and scalp should be thoroughly dry prior to topical application. Wash hands thoroughly after application.

**PHARMACOKINETICS**

On topical application minoxidil is poorly absorbed, from normal intact scalp with an average of 1.4% (0.3 to 4.5%) of the total applied dose, reaching systemic circulation. Therefore 1ml of minoxidil 5% delivering 50 mg Minoxidil to the skin, would result in absorption of 0.700 mg of minoxidil 5% respectively. Local abrasion or dermatitis may enhance absorption. Serum minoxidil levels resulting from topical administration are governed by the drugs absorption rate. Following cessation of topical dosing approximately 95% of systemically absorbed minoxidil is eliminated within 4 days. Metabolic biotransformation of minoxidil absorbed following topical application has not been fully determined.

**PRECAUTIONS AND WARNINGS**

- The safety and efficacy of the product in patients aged fewer than 18 or over 65 is unknown. Minoxidil topical solution should only be used on a normal healthy scalp.
- Do not use if scalp is inflamed, infected, irritated.
- Minoxidil topical solution should not be used concurrently with any other medicines on the scalp.
- Minoxidil topical solution is only indicated for the treatment of alopecia androgenetica and should not be used in other types 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.
- The patient should stop using Minoxidil topical solution and see a doctor if hypotension is detected or if the patient is experiencing chest pain, rapid heart-beat, faintness or dizziness, sudden unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp, or other unexpected new symptoms occur. Patients with known cardiovascular disease or cardiac arrhythmias should contact a physician before using Minoxidil topical solution.
- Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of the reach of children.
- Minoxidil topical solution is for external use only. Do not apply to areas of the body other than the scalp. Hands should be washed thoroughly after applying the solution. Inhalation of the spray mist should be avoided.
- Some patients have experienced changes in hair colour and/or texture with Minoxidil use.
- Some consumers reported increased hair shedding upon initiation of therapy with Minoxidil topical solution. This is most likely due to minoxidil's action of shifting hairs from the resting telogen phase to the growing

anagen phase (old hairs fall out as new hairs grow in their place). This temporary increase in hair shedding generally occurs two to six weeks after beginning treatment and subsides within a couple of weeks. If shedding persists (>2 weeks), users should stop using Minoxidil topical solution and consult their doctor.

- Users should be aware that, whilst extensive use of Minoxidil topical solution has not revealed evidence that sufficient minoxidil is absorbed to have systemic effects, greater absorption because of misuse, individual variability, unusual sensitivity or decreased integrity of the epidermal barrier caused by inflammation or disease processes in the skin (e.g. excoriations of the scalp, or scalp psoriasis) could lead, at least theoretically, to systemic effects.
- Using more than the recommended dose or applying more often will not improve results. Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again. Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp.

**Pregnancy & Lactation**

Minoxidil topical solution like other drugs should not be used by pregnant and nursing women.

**Pediatrics**

Safety and effectiveness of Minoxidil Topical Solution in patients under 18 years of age have not been established.

**SIDE EFFECTS**

Following undesirable effects have been reported:

Hypersensitivity reactions (including face edema, generalised erythema, pruritus generalised, swelling face, and throat tightness), Headache, dizziness, eye irritation, hypotension, palpitations, Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), Pruritus (including rash pruritic generalised and eye pruritus), Rash (including pustular, papular, generalised, vestibular and macular rash) and Dermatitis (including contact, allergic, atopic and seborrheic dermatitis).

**DRUG INTERACTIONS**

Topical minoxidil should not be used concurrently with any other medications on the scalp. Pharmacokinetic drug interaction studies in humans revealed percutaneous minoxidil absorption is enhanced by tretinoin and anhralin as a result of increased stratum corneum permeability; betmethasone dipropionate increases local tissue concentrations of minoxidil and

decreases systemic minoxidil absorption. Guanethidine has been reported to interact with oral formulations of minoxidil resulting in rapid and pronounced lowering of blood pressure.

#### **OVERDOSAGE**

Increased systemic absorption of minoxidil may potentially occur if higher-than-recommended doses of Minoxidil topical solution are applied to larger surface areas of the body or areas other than the scalp which therefore may lead to adverse events.

There is no evidence that topically applied minoxidil is absorbed in sufficient quantity to cause systemic effects. When used as directed, overdose is unlikely. Overdose due to oral administration or excessive systemic exposure of minoxidil exaggerates its cardiovascular effects and may present as hypotension, tachycardia and lethargy.

Because of the concentration of Minoxidil topical solution, accidental ingestion has the potential of producing systemic effects related to the pharmacological action of the drug. If this product is applied to an area of decreased integrity of the epidermal barrier caused by trauma, inflammation, or disease process in the skin, there is a potential for a systemic overdose effect.

Treatment of minoxidil over dosage should be symptomatic and supportive. Fluid retention can be managed with appropriate diuretic therapy.

#### **CONTRAINDICATIONS**

Minoxidil topical solution is contra-indicated:

- In users with a history of hypersensitivity to minoxidil or any of the excipients.
- In users with treated or untreated hypertension
- In users with any scalp abnormality (including psoriasis and sunburn)
- In users with a shaved scalp
- If occlusive dressings or other topical medical preparations are being used.

#### **STORAGE & INSTRUCTIONS**

Store below 25°C. Do not refrigerate or freeze.

Protect from heat and sunlight.

Keep away from the reach of the children.

**To be sold on the prescription of a registered medical practitioner only.** For scalp use only.

#### **HOW SUPPLIED**

60ml bottle with applicator.

خوراک و طریقہ استعمال:

بہتر نتائج کے لئے دن میں دو بار استعمال کریں۔ یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲۵ ڈگری سینٹی گریڈ درجہ حرارت سے نیچے رکھیں۔

دھوپ، گرمی اور نمند ہونے سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

صرف سر کی جلد پر استعمال کے لئے۔

Manufactured by:

**PHARMASOL**

**PRIVATE LIMITED**

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Lahore, Pakistan.