

## **Summary of Product Characteristic**

### **1. Trade Name of the Medicinal Product**

Minoxin Solution

### **2. Qualitative and Quantitative Composition**

Each ml contains:

Minoxidil

USP

..... 20

mg

### **3. Pharmaceutical Form**

Topical Solution

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indications**

It is indicated for the treatment of androgenetic alopecia, expressed in males as baldness of the vertex of the scalp and in females as diffuse hair loss or thinning of front parietal area. At least, 4 (four) months of twice daily application of Minoxin solution are generally required before evidence of hair growth can be expected.

#### **4.2. Posology and method of administration**

For eternal use only. Use Minoxin only as directed. Do not apply to any other area of the body. A total dose of 1ml Minoxin should be applied twice daily on the scalp, beginning at the center of the affected area. This dose should be used regardless of the size of the affected area. Six pumps of the applicator release approx. 1ml of Minoxin. The total daily dose should not exceed 2ml. To avoid any systemic absorption, wash hands thoroughly after applying Minoxin. Apply Minoxin when the hair and scalp are thoroughly dried. Don't use a hairdryer to speed the drying of Minoxin solution because blowing air on the scalp may decrease the effectiveness of Minoxin.

#### **4.3 Contraindications**

It is contraindicated in those patients with a history of hypersensitivity to any component of the preparation.

#### **4.4 Special warnings and precautions for use**

Although the following effects have not been associated with the topical use of Minoxidil solution there is some absorption (on average 1.4 %) from the scalp. The potential exists for systemic effects such as tachycardia, angina, oedema and potentiation of orthostatic hypotension produced by guanethidine. Patients should be observed periodically for any such systemic effects. In the event of systemic side-effect or severe dermatologic reaction discontinue administration of the drug.

Minoxin (Minoxidil Topical Solution USP) will cause burning and irritation to the eye. In the event of accidental contact with sensitive surface (eye, abraded skin, mucous membranes), the area should be bathed with copious amounts of cool tap water. Minoxin (Minoxidil Topical Solution USP) should not be used in conjunction with other topical agents including corticosteroids, retinoids and petrolatum or agents that are known to enhance cutaneous drug absorption.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

There are currently no interactions associated with the use of Minoxidil Topical Solution

#### **4.6 Fertility, pregnancy and lactation**

Systemically absorbed minoxidil is secreted in breast milk.

There are no adequate and well controlled studies in pregnant women. Animal studies have shown a risk to the fetus at exposure levels that are very high compared to those intended for human exposure. A low, albeit remote, risk of fetal harm is possible in humans.

Topical minoxidil should only be used during pregnancy or lactation if the benefit to the mother outweighs the potential risk to the fetus or nursing infant

#### **4.7 Effects on ability to drive and use machines**

Based on the pharmacodynamic and overall safety profile of topical minoxidil, it is not expected that Minoxin Solution would interfere with the ability to drive or operate machinery.

#### **4.8 Undesirable effects**

In placebo controlled trials, the overall frequency of adverse events in females in all body system categories was approximately five times that of males.

Several thousand patients have used topical minoxidil in clinical trials where a comparison with an inactive solution

was made. Dermatological reactions (e.g. irritation, itching) occurred in patients using both solutions. This has been explained by the presence of propylene glycol in both the active and inactive solution.

Data from 7 placebo controlled trials are available with a population of 1,197 males and females treated with topical minoxidil solution (2% and 5% combined) where adverse events were assessed. Additionally, adverse events reported in post-marketing are included.

*The frequency of adverse reactions to topical minoxidil solution is defined using the following convention*

*Very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1,000$ ,  $< 1/100$ ); rare ( $\geq 1/10,000$ ,  $< 1/1,000$ ); very rare ( $< 1/10,000$ ); not known (cannot be estimated from the available data).*

*The following adverse events were associated with placebo controlled clinical trials:*

<b>Body system</b>	<b>Incidence</b>	<b>Reported adverse event</b>
Nervous system disorders	Very common:	Headache
Vascular disorders	Common:	Hypertension*
Respiratory, thoracic and mediastinal disorders	Common:	Dyspnoea
Skin and subcutaneous tissue disorders	Common:	Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), pruritus, rash, (including rash pruritic and application site, pustular, papular, generalized vestibular and macular rash), eye pruritus acneform, dermatitis (including contact, application site, allergic, atopic and seborrhoeic

		dermatitis) and inflammatory skin disorder.
General disorders and administration site conditions	Common:	Oedema peripheral
Psychiatric disorders	Common:	Depression
Musculoskeletal	Common	Musculoskeletal pain
Miscellaneous	Common:	Pain

\* This adverse event was identified during a clinical trial for Minoxidil Foam  
*The following adverse events were associated with post marketing experience*

<b>Body system</b>	<b>Incidence</b>	<b>Reported adverse event</b>
Nervous system disorders	Rare	Headache
Vascular disorders	Uncommon	Hypotension
Cardiovascular disorders	Rare:	Palpitations Increased heart rate Chest pain

Skin and subcutaneous tissue disorders	Uncommon:	Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), temporary hair loss, changes in
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		hair texture and hair colour, skin exfoliation, dry skin and rash.
	Rare	Contact dermatitis

<b>Body system</b>	<b>Incidence</b>	<b>Reported adverse event</b>
General disorders and administration site conditions	Uncommon:	Application site irritation and application site pruritis
	Rare	Application site erythema.

### **Signs and symptoms**

There is no evidence that topically applied minoxidil is absorbed in sufficient quantity to cause systemic effects. When used as directed, overdose is unlikely.

Because of the high concentration of minoxidil in Minoxin Solution (5ml of 2% solution contains the maximum recommended adult dose (100mg) of minoxidil used orally in the treatment of hypertension), accidental ingestion of Minoxin Solution has the potential of producing systemic effects. Signs and symptoms of minoxidil over dosage would primarily be cardiovascular effects such as oedema, tachycardia, faintness or dizziness.

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.

The following very rare adverse events may occur due to the systemic effects of minoxidil;

#### Very Rare: (< 1/10,000)

Cardiovascular disorders: Heart rate increased, hypotension  
 General Disorders: Fluid retention resulting in weight increase  
 Nervous System Disorders: Dizziness

### **Treatment**

Treatment of minoxidil over dosage should be symptomatic and

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

**Reporting of suspected adverse reactions:**

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents

**4.9. OVERDOSE:**

**Signs and symptoms**

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**5. PHARMACOLOGICAL PROPERTIES:**

**5.1 PHARMACODYNAMIC PROPERTIES:**

Minoxin Solution stimulates hair growth in individuals with androgenetic alopecia in males (expressed as baldness of the vertex

of the scalp) and females (expressed as diffuse hair loss or thinning of the scalp).

The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can stabilize and reverse the hair loss process of androgenetic alopecia.

## **5.2 PHARMACOKINETIC PROPERTIES**

The failure to detect evidence of systemic effects during treatment with Minoxin Solution reflects the poor absorption of topical minoxidil, which averages about 1.4% (range 0.3-4.5%) of the total applied dose from normal intact skin. Absorption is about 2% when applied topically to shaved scalps of hypertensive patients. Increasing the amount of drug applied or increasing the frequency of application of Minoxin Solution also results in increased absorption. The use of Minoxin Solution in conjunction with occlusion (plastic dressings), application to sunburn areas, and increasing the surface area of application has minimal to no effect on the absorption of topical minoxidil. Results of extensive pharmacokinetic studies indicate that the three major factors by which topical minoxidil absorption are increased by are: Increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum. Serum minoxidil levels and systemic effects resulting from administration of Minoxin Solution are governed by the drug's absorption rate through the skin. Following cessation of topical dosing of Minoxin Solution, approximately 95% of the systemically absorbed drug is eliminated within 4 days. Minoxidil and its metabolites are excreted principally in the urine.

### **5.3 Preclinical safety data**

None that is relevant to human safety

## **2 PHARMACEUTICAL PARTICULARS**

### **6.1. LIST OF EXCIPIENTS:**

- Ethanol
- Propylene glycol injectable grade
- Purified-Water

### **6.2 INCOMPATIBILITIES:**

Not applicable

### **6.3 SHELF LIFE:**

2 years

**6.4 SPECIAL PRECAUTIONS FOR STORAGE:**

Do not store above 30°C. Protect from light .

**6.5 NATURE AND CONTENTS OF CONTAINER:**

Samples are stored as per the recommended packaging, i.e., in 60ml white opaque bottle made of H.D.P.E, sealed with P.E lined aluminum seal, having plastic cap further covered with cosmetic cap packed in unit carton, having another carton for spray pump, booklet and insert.

**6.6 Special precautions for disposal and other handling**

No special requirements.

**7. Marketing authorization**

**holder** Brookes Pharma  
Private Limited. Karachi –  
Pakistan

**8. Marketing authorization number**

9157

**9. Date of first / latest renewal of the authorization**

Date of first authorization : 11th February 1992

Date of renewal of authorization : 24th November 2021