

## PATIENT INFORMATION LEAFLET

### Minoxidil Scalp Application BP **SCALMIN 5%**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- ❖ Keep this leaflet. You may need to read it again.
- ❖ If you have any further questions, ask your doctor or pharmacist.
- ❖ This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- ❖ If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

#### What is in this leaflet:

1. What SCALMIN 5% is and what it is used for
2. What you need to know before you take SCALMIN 5%
3. How to use SCALMIN 5%
4. What are the possible side effects of SCALMIN 5%
5. How to store SCALMIN 5%
6. Contents of the pack and other information

#### 1. What SCALMIN 5% is and what it is used for

SCALMIN 5% is clear colourless to yellow solution. Colour may intensify on storage with no deleterious effect on efficacy of the medication. SCALMIN 5% solution is a medication containing Minoxidil for use in androgenic alopecia. SCALMIN 5% solution allows patients to re-grow normally thick and healthy hair. SCALMIN 5% solution is intended for both the crown of the scalp and frontal baldness (receding hairline).

SCALMIN solution containing 2% Minoxidil is indicated for men with male pattern baldness and women with female pattern baldness.

SCALMIN solution containing 5 / 10 % Minoxidil is indicated for androgenic alopecia only in men.

#### 2. What you need to know before you take SCALMIN 5%

Do not use SCALMIN 5% if you are allergic to Minoxidil.

#### Warnings and precautions

SCALMIN 5% solution may cause scalp irritation. If scalp irritation continues or worsens, use of SCALMIN 5% solution should be stopped.

Use of SCALMIN 5% solution should be stopped if the patient develops chest pain, rapid heartbeat, faintness or dizziness sudden and unexplained weight gain and swollen hands or feet.

SCALMIN 5% solution contains alcohol, which will cause burning and irritation of the eyes. In case of accidental contact with sensitive surfaces (such as eyes, abraded skin and mucous membranes), the area should be rinsed with large amounts of cool tap water. If needed the scalp can be washed with a mild shampoo before applying SCALMIN 5% solution. Hair sprays or hair styling aids may be used on the hair while using SCALMIN 5% solution, but for best results, it should be allowed to penetrate into the scalp before using any styling products.

Before colouring or perming hair or using hair relaxers the following precautions are recommended:

- ❖ To avoid possible scalp irritation, the SCALMIN 5% solution should be washed off the hair and scalp thoroughly.
- ❖ For best results application of SCALMIN 5% solution should be avoided.
- ❖ Do not use SCALMIN 5% solution for 24 hours after any perm or colour treatment to make sure that any chemicals used have not irritated the scalp. If no irritation occurs, continue use of SCALMIN 5% solution.

#### Drug Interactions

SCALMIN 5% solutions should not be used along with other topical agents known to alter the stratum corneum barrier such as tretinoin or dithranol, due to the enhanced absorption of Minoxidil. Although there is no clinical evidence, there exists the theoretical possibility of absorbed Minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

#### Use in Specific Populations

**Pregnancy:** There are no well controlled trials in pregnant women treated with Minoxidil Solution

Hence, SCALMIN 5% Solution is contraindicated in pregnant women.

**Nursing Mothers:** It is not known whether Minoxidil are excreted in human milk following topical application SCALMIN 5% Solution. Hence, SCALMIN 5% Solution is contraindicated in nursing women.

**Pediatric Use:** Safety and effectiveness of SCALMIN 5% Solution in children below 18 years of age have not been established.

**Geriatric Use:** Safety and effectiveness of SCALMIN 5% Solution in elderly patients above 65 years of age has not been established.

#### 3. How to use SCALMIN 5%

It is important for the complete action of the drug that the medicine reaches the scalp skin, during the time of application. Due care should be taken to rub the medicine on the scalp along with application on hair.

#### Directions for use:

SCALMIN 5% Solution must only be applied when the hair and scalp are completely dry. It can be applied with either of the two specialized applicators that help to direct product onto the scalp without losing it into the hair or environment.

#### A) Spray B) Dropper

##### A) Spray

Prime the spray pump by actuating it for 3 to 5 times in air.

After aiming the pump toward the centre of the bald area of the scalp, press the pump once and spread SCALMIN 5% with fingertips to cover all of the bald area. Repeat for a total of 5 times, to apply a dose of 1 ml of solution.

##### B) Dropper

1. Follow above steps of A1 & A2



1. Open the bottle.



2. Remove the seal.



3. Insert dropper into the bottle to fill the volume upto 1 ml line.



3. Pour the contents of the dropper aiming toward the centre of the bald area of the scalp and spread evenly with fingertips.

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Insert dropper into the bottle to fill the volume upto 1 ml line

The method of application varies according to the applicator used:

**Pump spray applicator:** Aim the pump at the centre of the bald area, press once and spread with fingertips over the entire bald area. Repeat for a total of five times to apply a dose of 1 ml. Avoid breathing spray mist.

**Dropper:** Fill the dropper to the 1 ml mark and apply the SCALMIN 5% solution to the bald area until the entire dose has been delivered.

SCALMIN 5% solution should be applied when the hair and scalp are clean and dry. Apply 1ml of SCALMIN 5% solution twice daily at 12-hour intervals to the scalp, beginning at the centre of the affected area and spreading the solution out to cover the entire affected area. The total daily application dose should not exceed 2 ml. For best results, SCALMIN 5% solution should be allowed to remain on the scalp for about 4 hours before washing. The night-time application should be done 2-4 hours before going to bed to allow the solution to dry out.

SCALMIN 5% solution should not be massaged into the scalp, but applied lightly. A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness. SCALMIN 5% solutions should not be mixed with any hair oil.

The drug should not be used more than two times a day, or be taken orally or applied to any other part of the body to avoid the risk of adverse effects and unwanted hair growth.

More frequent use or longer application time have no effect on hair growth. In case of missing any daily applications of SCALMIN 5% solution, the patient should continue with the next application.

Clinical experience with minoxidil indicates that twice-daily applications for 2 months or more may be required before there is evidence of hair growth. To arrest hair fall, SCALMIN 5% solution should be used for not less than 45 days.

When you first begin to use SCALMIN 5%, your hair loss may increase temporarily, increase in hair loss indicates shedding of old hair for new hair growth. If increase in hair loss continues after 2 weeks, discontinue use and consult your doctor.

Treatment with SCALMIN 5% is long term therapy for hair regrowth. In case of response to treatment, it is advisable to continue the treatment for hair growth and also to stop additional hair loss.

#### Contraindications

Patients with a history of hypersensitivity to any of the ingredients of the formulation.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody experiences them. In addition to the beneficial effects of minoxidil, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

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

Very common (1/10); common (1/100, <1/10); uncommon (1/1000, <1/100); rare (1/10000, <1/1000); very rare (1/10000, <1/1000); not known (cannot be estimated from the available data).

Body system	Incidence	Reported adverse event
Nervous system disorders	Common	Headache
Vascular disorders	Uncommon	Hypotension
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea
Skin and subcutaneous tissue disorders	Common	Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), pruritus (including rash pruritic and application site, generalized and eye pruritus)
	Uncommon	Temporary hair loss, changes in hair texture and hair colour, skin exfoliation (including application site, exfoliative rash) and dermatitis exfoliative), rash (including application site, pustular, papular, generalized vestibular and macular rash), acne (acne form rash), dermatitis (including contact, application site, allergic, atopic and seborrhoeic dermatitis) and dry skin (including application site dryness)
General disorders and administration site conditions	Uncommon	Oedema peripheral, Application site irritation (including skin irritation), application site erythema (including erythema and rash erythematous)

Users should stop using SCALMIN 5% solution if they experience chest-pain, tachycardia, faintness, dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness or irritation of the scalp.

#### Overdosage

Increased systemic absorption of minoxidil may potentially occur if higher than recommended doses of SCALMIN 5% solution are applied to larger surface areas of the body or areas other than the scalp.

Because of the concentration of minoxidil in SCALMIN 5% solution, accidents ingestion has the potential of producing systemic effects related to the pharmacological action of the drug. Signs and symptoms of minoxidil overdose would primarily be cardiovascular effects associated with sodium and water retention, tachycardia and hypotension.

Treatment of minoxidil overdose should be symptomatic and supportive.

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#### Reporting of side effects

If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store SCALMIN 5%

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after Exp: The expiry date refers to the last day of that month.

Store below 25°C. Do not freeze. Protect from light.

#### Contents of the pack and other information

The active ingredient is Minoxidil

Composition:

Minoxidil USP 5% w/w

In an adhesive base q.s.

Ethanol 95% IP equivalent to Ethanol 40% v/v

#### What SCALMIN 5% looks like and contents of the pack

SCALMIN 5% is clear colourless to yellow solution. SCALMIN 5% is available in 60ml white HDPE bottle with spray pump applicator/dropper.



Manufactured by :  
**Quest Pharmaceuticals Pvt. Ltd.**  
Chhata Pipara, Bara, Nepal

*For further information*  
**Quest Pharmaceuticals Pvt. Ltd.**  
Tripureshwar, Kathmandu  
Tel. 01-4240304, Email : quest.ktm@quest.com.np,  
Website : www.quest.com.np