For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name

Minoxidil Topical Solution USP 5% w/v

Minichek® Ultra

2. Qualitative and Quantitative Composition:

Composition:
Minoxidil I.P……5% w/v
Aqueous base……...q.s.

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

Treatment of androgenetic alopecia (male pattern baldness) in men.

4.2 Posology and method of administration

Minichek topical solution is used for external use only. It should be applied twice daily, once in the morning and once at night onto clean, dry scalp, in the hair loss area. The total spray should not exceed over 6 sprays (1 ml). For Minichek to work best, it should be allowed to remain on the scalp for about 4 hours before washing. The nighttime application should occur 2 to 4 hours before going to bed to allow drying.

The drug should not be used more frequently than 2 times a day or should not be taken by mouth or applied to any other part of the body to avoid risk of adverse effects and unwanted hair growth. Hands should be washed if Minichek solution is applied with finger tips. In case of missing one or two daily doses of Minichek, patient should continue with the next dose.

4.3 Contraindications

- Children under 18 years of age
- In woman
- Patient with history of hypersensitivity to minoxidil or propylene glycol.
- Patients with treated or untreated hypertension.
- Minichek should not be used in patients whom the reason for hair loss is unknown. Minichek solution will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Minichek solution will not improve hair loss due to damage from the use of hair care products, which cause scarring or deep burns of the scalp and hair grooming methods.
- Patients using occlusive dressings or other medications on the scalp.
- Patients with inflamed, infected, irritated or painful scalp conditions (including psoriasis and sunburn)

4.4 Special warnings and precautions for use

Minichek solution should be stopped if the patient develops chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain & swollen hands or feet. Hair sprays or hair styling aids may be used on the hair while using Minichek solution but for best results it should be allowed to penetrate into the scalp before using any styling products.

Before going for hair coloring or perming or use of relaxers the following precautions are recommended:

1. To avoid possible scalp irritation, all of Minichek solution should be washed off the hair and scalp before using the color or perm chemicals.
2. For best results, application of Minichek solution and chemical treatments to hair on the same day should be avoided.

3. Do not use Minichek solution for 24 hours after using any chemicals to make sure that the scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue to use Minichek solution.

Use in special populations:

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Studies in animals have shown a risk to the fetus at exposure levels that are very high compared to those intended for human exposure. There is potentially a risk of fetal harm in humans.
Lactation
Systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.
Pediatrics
Safety and efficacy not established.
Geriatrics
The efficacy and safety of Minichek solution is not established in elderly people above 65 years of age, hence its use in elderly is not recommended.

4.5 Drug Interactions
This product 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.
Guanethidine has been reported to interact with oral formulations of minoxidil resulting in rapid and pronounced lowering of blood pressure.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)
This product should not be used during pregnancy or lactation.
Pregnancy
There are no adequate and well-controlled studies in pregnant women. Studies in animals have shown a risk to the fetus at exposure levels that are very high compared to those intended for human exposure. There is potentially a risk of fetal harm in humans.
Lactation
Systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.
Paediatric and Elderly Populations
Not recommended. The safety and effectiveness of Minoxidil 5% in children and adolescents below the age of 18 years or adults over 49 years old has not been established.

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

4.8 Undesirable effects

Body System (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Immune System Disorders	Common	Hypersensitivity reactions including: face oedema, generalised erythema, pruritus generalised, swelling face, and throat tightness)
	Not known	Angioedema (including: lip oedema, lip swelling, oedema mouth, oropharyngeal swelling, pharyngeal oedema, swollen tongue and tongue oedema)
Psychiatric Disorders	Not known	Depressed mood

Nervous System Disorders	Very common	Headache
	Uncommon	Dizziness
Eye disorders	Not known	Eye irritation
Cardiac disorders	Common	Chest pain
	Uncommon	Palpitations
	Not known	Heart rate increased
Vascular disorders	Not known	Hypotension
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea
Gastrointestinal Disorders	Uncommon	Nausea
	Not known	Vomiting
Skin and subcutaneous tissue disorders	Common	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) Dermatitis (including contact, allergic, atopic and seborrhoeic dermatitis)
	Rare	Changes in hair texture
	Not known	Dry skin Skin exfoliation (including exfoliative rash and dermatitis exfoliative) Acne (acneiform rash) Temporary hair loss (see section 4.4) Changes in hair colour
General disorders and administration site conditions	Common	Oedema peripheral
	Not known	Application site reactions (These sometimes involve nearby structures like the ears and face and typically consist 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

4.9 Overdose

Over dosage with Minoxidil results from systemic absorption, which may occur if the Minichek solution is applied too frequently, or if it is applied to large surface areas of the body or areas other than the scalp or if ingested. There is no data of minoxidil over dosage resulting from topical administration.

Signs & symptoms of minoxidil over dosage as a result of accidental ingestion or deliberate overdose would primarily be the cardiovascular effects associated with the sodium and water retention and tachycardia. Treatment should include diuretic therapy to manage fluid retention and beta-adrenergic blocking drugs for controlling significant tachycardia.

5. Pharmacological properties

5.1 Mechanism of action

The mechanism by which minoxidil stimulates hair growth is not established, but possible mechanism includes:

- Direct mitogenic effect on epidermal cells
- Prolongation of the survival time of keratinocytes
- Opposition to intracellular calcium entry, which normally enhances epidermal growth factors to inhibit hair growth.

5.2 Pharmacodynamic Properties

Minichek is for treating male pattern baldness. All patients may not be responsive to topical Minichek solution treatment. The amount of hair growth differs from person to person. Although data suggest that those users 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 Minichek solution, individual responses cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

Twice daily application of the Minichek solution directly on the scalp for 2-4 months is required before the evidence of hair regrowth. If hair regrowth is not seen after 4 months, treatment with Minichek solution should be stopped. Initial treatment with Minichek solution results in temporary increase in hair loss for upto 2 weeks. This is likely due to replacement of telogen hair by the anagen phase hair. If the increase in hair loss is more than 2 weeks, Doctor consultation is advised. Continuous used of Minichek solution is needed to maintain hair regrowth. New hair grown during therapy may be expected to be lost 3-4 months after withdrawal of Minichek and progressive hair loss will resume.

5.3 Pharmacokinetic properties

The failure to detect evidence of systemic effects during treatment reflects the poor absorption of topically applied minoxidil from normal intact skin. Systemic absorption of minoxidil from topically applied solution ranges between 1% and 2% of the total applied dose.

The systemic absorption of minoxidil from a 5% solution formulation has been reported in a pharmacokinetic study in subjects with androgenetic alopecia, which included 5% topical foam as a comparator. This demonstrated that in men, the systemic absorption of minoxidil from twice daily application of 5% minoxidil solution was about twice that observed with 5% minoxidil foam. The mean steady state AUC(0-12 h) and Cmax for 5% minoxidil 5% solution were 18.71 ng·h/ml and 2.13 ng/ml, respectively. The time to maximum minoxidil concentration (Tmax) for the 5% solution was 5.79 hours.

There is some evidence from reported in vitro studies that minoxidil reversibly binds to human plasma proteins. However, since only 1 – 2% of topically applied minoxidil is absorbed, the extent of plasma protein binding occurring in vivo after topical application would be clinically insignificant. The volume of distribution of minoxidil after intravenous administration has been reported at approx. 70 litres.

Approximately 60% minoxidil absorbed after topical application is metabolised to minoxidil glucuronide, primarily in the liver. Minoxidil and its metabolites are excreted almost entirely in the urine, with a minor degree of elimination via the faeces. Following cessation of dosing, approximately 95% of topically applied minoxidil will be eliminated within four days.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Mutagenicity

Minoxidil showed no evidence of mutagenic/genotoxic potential in a number of in vitro and in vivo assays.

Carcinogenicity

A high incidence of hormone-mediated tumors was observed in mice and rats. These tumors are due to the secondary hormonal (hyperprolactinemia) effects observed only in the rodents at extremely high doses by a mechanism similar to that seem with reserpine. Application of topical minoxidil has not demonstrated any effect on hormonal status in women. Therefore, hormonally mediated tumor promotion by minoxidil does not represent a carcinogenic risk to humans.

Teratogenicity

Animal reproduction toxicity studies in rats and rabbits have shown signs of maternal toxicity and 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.

Fertility

Minoxidil doses greater than 9 mg/kg (at least 25-fold human exposure) administered subcutaneously in rats were associated with reduced conception and implantation rates as well as reduction in the number of live pups.

7. Description

Minichek Ultra is supplied for topical use, as Topical solution of Minoxidil. Each bottle of Minichek Ultra contains Minoxidil 5 % w/v.

8. Pharmaceutical particulars

8.1 Incompatibilities
NA

8.2 Shelf Life
Refer Pack

8.3 Packaging Information
Refer Pack

8.4 Storage condition & handling instructions
Refer Pack

9. Patient Counseling Information

- Patients should be counselled that treatment for AGA is lifelong and hence they should be compliant with the same. Patients should also be advised on the proper usage and precautions to be taken when using Minichek 5% in order to avoid any adverse effects.
- Patient should be informed Minichek topical solution is used for external use only. The total spray should not exceed over 6 sprays (1 ml). For Minichek to work best, it should be allowed to remain on the scalp for about 4 hours before washing. The nighttime application should occur 2 to 4 hours before going to bed to allow drying.
- Patient should be informed that the drug should not be used more frequently than 2 times a day or should not be taken by mouth or applied to any other part of the body to avoid risk of adverse effects and unwanted hair growth. Hands should be washed if Minichek solution is applied with fingertips. In case of missing one or two daily doses of Minichek, patient should continue with the next dose.
- Patient should be informed Minichek solution will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Minichek solution will not improve hair loss due to damage from the use of hair care products, which cause scarring or deep burns of the scalp and hair grooming methods.
- Patient should be informed Minichek solution should be stopped if the patient develops chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain & swollen hands or feet. Hair sprays or hair styling aids may be used on the hair while using Minichek solution but for best results it should be allowed to penetrate into the scalp before using any styling products.
- Before going for hair coloring or perming or use of relaxers the following precautions are recommended to the patient:
    - To avoid possible scalp irritation, all of Minichek solution should be washed off the hair and scalp before using the color or perm chemicals.
    - For best results, application of Minichek solution and chemical treatments to hair on the same day should be avoided.
    - Do not use Minichek solution for 24 hours after using any chemicals to make sure that the scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue to use Minichek solution.
- Patients should be informed that there is potentially a risk of foetal harm in humans.
- Patients should be informed that systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.
- Patients should be informed that Minichek is not recommended in Paediatric and Elderly Populations. The safety and effectiveness of Minoxidil 5% in children and adolescents below the age of 18 years or adults over 49 years old has not been established.

- Patients should be informed that Minichek may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.
- Patients should be informed that the following undesirable effects can be seen - Irritation, eczema, hypertrichosis, allergic contact dermatitis, local erythema, exacerbation of hair loss, burning, respiratory infections, tendinitis, back pain, fractures, sinusitis, edema, anxiety, erythema at site of application and systemic effects including hypotension, dizziness, light-headedness, and fainting.
- Patients should be informed that over dosage with Minoxidil results from systemic absorption, which may occur if the Minichek solution is applied too frequently, or if it is applied to large surface areas of the body or areas other than the scalp or if ingested.
- Patients should be informed that cardiovascular effects can be seen due to minoxidil over dosage as a result of accidental ingestion or deliberate overdose and would primarily be associated with the sodium and water retention and tachycardia.

10. Details of manufacturer
Refer Pack for manufacturer details.

Marketed by:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
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11. Details of permission or licence number
Refer Pack for Permission/License details.

12. Date of revision
Version 2.0, dated 20th August 2025

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**