For the Use of a Registered Medical Practitioner Only

1. Generic Name & Brand Name

Minoxidil with Finasteride Lipid Solution for Topical Application
Minichek® F

2. Qualitative and Quantitative Composition

Composition:
Minoxidil I.P. 5% w/v
Finasteride I.P. 0.1% w/v
Excipients: Butylene Glycol (and) Water (and) PPG-26-Buteth-26 (and) PEG 40, Hydrogenated castor oil (and) Apigenin (and) Oleanolic Acid (and) Biotinoyl Tripeptide-1
In a base q.s.

3. Dosage Form and Strength

Kindly refer to section 1 & 2

4. Clinical Particulars

4.1 Therapeutic Indication

For the treatment of androgenic alopecia in males.

4.2 Posology And Method of Administration

For external use only. Use only as directed.
A total dose of 1 ml Minichek F 5% topical solution should be applied twice per day to the affected scalp, beginning at the center of the area. This dose should be used regardless of the size of the affected area. The total daily dose should not exceed 2 ml. Minichek F 5% topical solution should be applied when the hair and scalp are thoroughly dry. Do not use a hairdryer to speed the drying of the topical solution, because blowing air on the scalp may decrease the effectiveness of the drug. Minichek F 5% should be allowed to completely dry for 2 to 4 hours after applying it, including before going to bed. Minichek F 5% may stain clothing, hats or bed line if the hair or scalp is not fully dry after the medicine.

Minichek F 5% solution shall not be mixed with any hair oil nor shall it be applied to other body parts. Hands should be thoroughly washed after application.
Clinical experience with minoxidil solution and finasteride indicates that application for 4 or more months may be required before evidence of hair growth stimulation can be expected. Onset and degree may be variable among patients. Though relapse to pretreatment appearance following discontinuation of minoxidil solution use has been anecdotally reported to occur within 3 to 4 months, it is expected that Minichek F 5% Solution shall not demonstrate the same due to additional benefits of finasteride.

4.3 Contraindications

- Hypersensitivity to minoxidil, finasteride or any of the constituents of the solution

- Pregnancy and lactation

4.4 Special Warnings and Precautions For Use

There is some absorption of minoxidil from the skin and the potential exists for systemic effects such as tachycardia, angina, edema or potentiation of the orthostatic hypotension produced by guanethidine. Patients should be observed periodically for any suggestion of systemic effects of minoxidil. In the event of systemic side effects discontinue administration of the drug. If necessary, fluid retention and edema can be managed with diuretic treatment.

Tachycardia and angina can be controlled by administration of beta adrenergic blocking drugs or other sympathetic nervous system suppressants. Though not expected, finasteride on percutaneous absorption can suppress the serum DHT levels and may cause systemic side effects i e decreased libido, erectile dysfunction, ejaculation disorders, breast tenderness or enlargement and testicular pain. Patients should be observed periodically for any suggestion of such systemic effects. Especially caution should be used in patients with liver function abnormalities as finasteride is metabolized extensively in the liver. Serum Prostate Specific Antigen levels: Percutaneous absorption of finasteride may affect serum PSA levels. These shall be taken into account for proper interpretation of serum PSA when evaluating men treated with Minichek F 5 %.

If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus.

4.5 Drugs Interactions

There are currently no known drug interactions associated with the use of minoxidil or finasteride topical administration. Although it has not been clinically demonstrated, there exists the possibility of minoxidil potentiating orthostatic hypotension in patients concurrently taking guanethidine.

4.6 Use in Special Populations

Pregnancy and Lactation:

Minichek F 5% should not be used by pregnant or nursing women. Because of the ability of Type II 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride.

Children: Safety and effectiveness of Minichek F 5% in patients under 18 years of age has not been established.

Patients with Underlying Cardiovascular Disease: Patients should not use minoxidil topical solution if they have a history of underlying coronary artery disease, cardiac dysrhythmias, congestive heart failure or valvular heart disease. Patients with hypertension, including those under treatment with antihypertensive agents, should be monitored closely and their medication adjusted if necessary. Minichek F 5% should be used with caution in patients with any other cardiovascular disease present.

Geriatrics: Studies involving subjects over the age of 60 years have not been performed hence the safety and effectiveness of Minichek F 5 % in these patients has not been established.

4.7 Effects on Ability to Drive and Use Machines
Data not available

4.8 Undesirable Effects
The most frequently encountered adverse effects in clinical trials with minoxidil topical solution were minor dermatologic reactions. Local irritation was the most common adverse reaction reported including scaling erythema / flushing, dermatitis, dry skin, hypertrichosis (in areas other than where minoxidil topical solution was applied) burning sensation and rash. Infrequent adverse reactions reported with minoxidil solution include allergic reactions (sensitivity, hives, generalized erythema and facial swelling); dizziness, tingling sensation; headache; weakness; neuritis; edema, eye irritation, altered taste, ear infection (otitis externa); and visual disturbances. Rarely reported adverse reactions included alopecia, hair abnormalities, chest pain, blood pressure changes, pulse changes, hepatitis and Kidney stones. The frequently reported adverse events with finasteride oral administration are impotence, decreased libido, ejaculation disorders, breast enlargement or tenderness and skin rash. These side effects resolve mostly despite continuation of therapy. In the others discontinuation of treatment resolves them. Physicians should instruct their patients to promptly report any changes in their breasts such as lumps, pain or nipple discharge as breast changes including breast enlargement, tenderness and neoplasm have been reported during finasteride treatment.
Allergic reactions including angioedema as an undesirable effect with an unknown frequency.

4.9 Overdose
Accidental ingestion of minoxidil topical solution may produce systemic effects related to the vasodilatory action of minoxidil. There have been only a few instances of deliberate or accidental over dosage with oral minoxidil. Signs and symptoms of drug over dosage would most likely include cardiovascular effects associated with fluid retention, lowered blood pressure and tachycardia. Fluid retention can be managed with appropriate diuretic therapy. Tachycardia can be controlled by administration of a beta-adrenergic blocking agent. There have been no reports of specific adverse events with the high doses of finasteride. Currently, no specific treatment for an overdose with finasteride is recommended.

5. Pharmacological Properties
5.1 Mechanism of Action
(Refer section 5.2)

5.2 Pharmacodynamic Properties
When applied topically, minoxidil topical solution has been shown to stimulate hair growth in individuals with alopecia androgenetica (male pattern baldness) .Although the

exact mechanism of action of minoxidil in the treatment of alopecia androgenetica is not known, there may be more than one mechanism by which minoxidil stimulates hair growth, they include (a) vasodilation of the microcirculation around the hair follicles which may stimulate hair growth, (b) direct stimulation of the hair follicle cells to enter into a proliferative phase (anagen) follicles; (c) alteration of the effect of androgens on genetically predetermined hair follicles; minoxidil may affect the androgen metabolism in the scalp by inhibiting the capacity of androgens to affect the hair follicles. In men with male pattern hair loss (androgenetic alopecia), the balding scalp contains miniaturized hair follicles and increased amounts of DHT compared with hairy scalp. Application of finasteride decreases scalp DHT concentration in these men, which may contribute to the treatment effect of finasteride. By this mechanism, finasteride appears to interrupt a key factor in the development of androgenetic alopecia in those patients genetically predisposed.

5.3 Pharmacokinetic Properties

Following topical application of minoxidil topical solution, minoxidil is poorly absorbed form normal intact skin, with an average of 1.4% (range 0.3 to 4.5%) of the total applied dose reaching the systemic circulation. The effects of concomitant dermal diseases or occlusion on absorption are unknown. Serum minoxidil levels resulting from topical administration are governed by the drug's percutaneous absorption rate; increases in surface area of application do not result in proportionate increases in the serum minoxidil level. Steady state is achieved by the end of the third dosing interval (36 hours) when the drug is administered twice daily. Approximately 95% of the systemically absorbed minoxidil from topical dosing is eliminated within 4 days. The metabolic biotransformation of minoxidil absorbed following topical application has not been fully determined.

Known metabolites exert much less pharmacologic effect than minoxidil itself, and all are excreted principally in the urine. Minoxidil does not bind to plasma proteins; its renal clearance corresponds to glomerular filtration rate and it does not cross the blood brain barrier. Minoxidil and its metabolites are hem dialyzable, although this does not rapidly reverse its pharmacological effect.

Increased hair growth has not been associated with increased systemic absorption of topical minoxidil. The onset of hair growth stimulation requires twice daily applications of minoxidil topical solution for 4 or more months and is variable among patients. Upon discontinuation of topically applied minoxidil, new hair growth has been anecdotally reported to stop and restoration of pretreatment appearance to occur within 3 to 4 months.

The pharmacokinetics of finasteride following topical administration has not been evaluated systematically. However, it is expected that it will be poorly absorbed form normal intact skin, with a minimal of the total applied dose reaching the systemic circulation.

6. Nonclinical Properties

6.1 Animal Toxicology or Pharmacology

Data not available

7. Description

Minichek F is supplied as a Lipid Solution for Topical Application. Each ml of Minichek F contains Minoxidil 5% w/v & Finasteride 0.1% w/v.

8. Pharmaceutical Particulars

8.1 Incompatibilities

Not Applicable

8.2 Shelf-Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage and Handing Instructions

Refer Pack

9. Patient Counselling 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 F 5% in order to avoid any adverse effects.

Do not apply on other parts of the body

Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.

A total dose of 1 ml Minichek F 5% topical solution should be applied twice per day to the affected scalp, beginning at the center of the area.

This dose should be used regardless of the size of the affected area.

The total daily dose should not exceed 2 ml. Minichek F 5% topical solution should be applied when the hair and scalp are thoroughly dry.

Do not use a hairdryer to speed the drying of the topical solution, because blowing air on the scalp may decrease the effectiveness of the drug.

Minichek F 5% should be allowed to completely dry for 2 to 4 hours after applying it, including before going to bed.

Minichek F 5% may stain clothing, hats or bed line if the hair or scalp is not fully dry after the medicine.

Minichek F 5% solution shall not be mixed with any hair oil nor shall it be applied to other body parts

. Hands should be thoroughly washed after application.

Clinical experience with minoxidil solution and finasteride indicates that application for 4 or more months may be required before evidence of hair growth stimulation can be expected. Onset and degree may be variable among patients.

Stop use and ask a doctor if

■ chest pain, rapid heartbeat, faintness, or dizziness occurs
■ sudden, unexplained weight gain occurs
■ your hands or feet swell
■ scalp irritation or redness occurs
■ unwanted facial hair growth occurs
■ you do not see hair regrowth in 4 months

Should not be used when pregnant or breast-feeding. Consult with your prescribing doctor for further details.
Keep out of reach of children. If swallowed, get medical help.

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
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

11. Details of Permission or Licence Number
Refer Pack for Permission/License details.

12. Date of Revision
Version 3.0, dated 02nd July 2025

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