

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

Regaine For Men Extra Strength Scalp Foam 5% w/w Cutaneous Foam (minoxidil) Product Information

Presentation:

Cutaneous foam containing minoxidil 50mg/g (5% w/w).

Uses:

Treatment of alopecia androgenetica in men aged 18 to 49.

Dosage:

1g twice daily to affected areas of scalp. Maximum dose 2g in 24 hours.

Contraindications:

Hypersensitivity to ingredients. Hypertension, scalp abnormality, shaved scalp, occlusive dressings on scalp or other topical medications. Also contraindicated for use in women.

Precautions:

For external use only on normal healthy scalp. Wash hands thoroughly after application. Avoid contact between children and minoxidil application sites, as cases of reversible hypertrichosis have been reported in infants following skin contact with application sites of patients/caregivers who were using topical minoxidil. Avoid contact with eyes or sensitive surfaces. Stop use and see doctor if hypotension or other cardiovascular symptoms of systemic absorption develops. Patients with cardiovascular disease or arrhythmia should contact physician before use. Foam contains 536.3mg of alcohol (ethanol) in each 1g. It may cause burning sensation on damaged skin. Ethanol may cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces the area should be bathed with large amounts of cool tap water. Foam also contains butylated hydroxytoluene, cetyl and stearyl alcohol which may cause local skin reactions. This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.

Pregnancy and Lactation:

Should not be used.

Side effects:

Very common: headache.

Common: hypersensitivity reactions, chest pain, hypertrichosis, pruritus, rash, dermatitis, oedema peripheral and weight increase.

Uncommon: dizziness, palpitations, dyspnoea, and nausea

Rare: changes in hair texture

Not known: angioedema, depressed mood, eye irritation, heart rate increased, hypotension, vomiting, dry skin, skin exfoliation, acne (acneiform rash), temporary hair loss, changes in hair colour and application site reactions.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex VAT): Single pack- £32.67; Triple pack- £75.14

Legal category: GSL.

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK.

PL Number(s): 15513/0366.

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