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 Women Once a Day 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 women (also known as female pattern hair loss) in women aged between 18 and 65.

Dosage:

1g once daily to the total affected areas of scalp. Maximum dose 1g in 24 hours.

Contraindications:

Hypersensitivity to ingredients, hypertension, scalp abnormality, shaved scalp, occlusive dressings on scalp or other topical medications. Contraindicated for use in men.

Precautions:

For external use only on normal healthy scalp. Wash hands thoroughly after application. 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 to contact physician before use. Product contains 536.3 mg of alcohol (ethanol) in each 1 g. It may cause burning sensation on damaged skin. Ethanol may cause burning and irritation of the eye. Product 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.

<u>Common</u>: hypersensitivity reactions, chest pain, hypertrichosis, pruritus, rash,

dermatitis, oedema peripheral and weight increase.

Uncommon: dizziness, palpitation, dyspnoea, and nausea

Rare: changes in hair texture

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

RRP (ex VAT): Single Pack-£32.67, Double pack - £44.46.

Legal category: GSL

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe

Buckinghamshire, HP12 4EG PL Number(s): 15513/0135. Date of prep: 14 February 2023