Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Regaine for Men Extra Strength Scalp Foam 5% w/w Cutaneous Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minoxidil 50 mg/ g
Each gram of cutaneous foam contains 50 mg minoxidil (5% w/w).

Excipient(s) with known effect:
1 g of cutaneous foam contains 564.6 mg of ethanol, 1 mg of butylhydroxytoluene, 5.30 mg of stearyl alcohol, 11.60 mg of cetyl alcohol and 4.20 mg of polysorbate 60.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam
White to yellowish, unscented foam.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of androgenetic alopecia in adult men.

4.2 Posology and method of administration

Posology
Regaine is for topical use only. Do not apply to areas of the body other than the scalp.

Hair and scalp should be thoroughly dry prior to topical application of the foam. For men aged 18 years or above a dose of 1 g (equivalent to the volume of half a capful) of Regaine should be applied to the total affected areas of the scalp twice daily (once in the morning and once in the evening). The maximum total daily recommended dose of topical minoxidil in men is 100mg, administered as up to 2 g foam per day.

Duration of use

It may take twice-daily applications for 2 to 4 months before evidence of hair growth can be expected. Users should discontinue use if there is no improvement seen after 4 months.

If hair regrowth occurs, twice daily applications of Regaine are necessary for continued hair growth.

Special populations
There are no specific recommendations for use in elderly patients or in patients with renal or hepatic impairment.

Pediatric population
Regaine is not recommended for use in children below the age of 18 years due to lack of data on safety and efficacy.

Method of administration
Hold can upside down and press the nozzle to dispense foam onto the hand. Spread with fingertips over entire bald area. Hands should be washed thoroughly after application.

4.3 Contraindications

Hypersensitivity to minoxidil or to any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Regaine should be used when the scalp is normal and healthy and should not be applied to inflamed infected, irritated or painful scalp skin.

Regaine is not indicated when there is no family history of hair loss, hair loss is sudden and/or patchy, or the reason for hair loss is unknown.

Using more than the recommended dose or applying more often will not improve results.

Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again.

Regaine should not be used concurrently with any other medicines on the scalp.
Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp.

Cardiovascular effects

Patients with known cardiovascular disease or cardiac arrhythmia should contact a physician before using Regaine.

Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of the reach of children.

Symptoms necessitating discontinuation of use and medical advice

The patient should stop using Regaine and see a doctor if hypotension is detected or if the patient is experiencing chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness or irritation of the scalp, or other unexpected new symptoms (see section 4.8).

Changes in hair colour and/or texture

Some patients have experienced changes in hair colour and/or texture with Regaine use.

Temporary hair shedding

Increased hair shedding can occur due to minoxidil's action of shifting hairs in the resting telogen phase to the growing anagen phase (old hairs fall out as new hairs grow in their place). This temporary increase in shedding generally occurs two to six weeks after beginning treatment and subsides within a couple of weeks (first sign of action of minoxidil). If shedding persists users should stop using Regaine and consult their doctor.

Potential systemic effects

Users should be aware that, whilst extensive use of Regaine has not revealed evidence that sufficient minoxidil is absorbed to have systemic effects, greater absorption because of misuse, individual variability, unusual sensitivity or decreased integrity of the epidermal barrier caused by inflammation or disease processes in the skin (e.g. excoriations of the scalp, or scalp psoriasis) could lead, at least theoretically, to systemic effects.

Hypertrichosis in children following inadvertent topical exposure to minoxidil

Hypertrichosis in children following inadvertent topical exposure to minoxidil:
Cases of hypertrichosis have been reported in infants following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hypertrichosis was reversible, within months, when infants were no longer exposed to minoxidil. Contact between children and minoxidil application sites should therefore be avoided.

Excipients

Regaine contains 564.6 mg alcohol (ethanol) in each dosage unit (1 g), which is equivalent to 56.46 % w/w. It may cause burning sensation on damaged skin. In the event of accidental contact with sensitive surfaces (eye, abraded skin and mucous membranes) the area should be bathed with large amounts of cool tap water.

Regaine also contains butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes or mucous membranes, and cetyl and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains polysorbate which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Regaine should not be used concomitantly with other medications applied topically on the scalp.

Pharmacokinetic drug interaction studies in humans revealed percutaneous minoxidil absorption is enhanced by tretinoin and dithranol, as a result of increased stratum corneum permeability.

4.6 Fertility, pregnancy and lactation

Regaine should not be used by women.

Fertility

There are no adequate and well controlled studies in relation to women's fertility.
Studies in animal have shown fertility toxicity a reduced conception and implantation rates as well as reduction in the number of live pups at exposure levels that are very high compared to those intended for human exposure (see section 5.3). The potential risk in human is unknown.

Pregnancy

There are no adequate and well-controlled studies in pregnant women.
Studies in animal have shown a risk to the foetus at exposure levels that are very high compared to those intended for human exposure (see section 5.3). The potential risk in humans is unknown.

Breast-feeding

Systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.

Regaine is not recommended during pregnancy or lactation and to women of childbearing potential not using contraception

4.7 Effects on ability to drive and use machines

Minoxidil may cause dizziness or hypotension. If patients are affected they should not drive or operate machinery.

4.8 Undesirable effects

The safety of topical minoxidil from clinical trials data is based on data from two placebo-controlled randomized clinical trials in adults evaluating a 5% foam formulation.

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with minoxidil are included in the table by system Organ Class (SOC).

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

Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

Body system	Incidence	Reported adverse event
Immune System Disorders	Not known	Allergic reactions including angioedema

Body system	Incidence	Reported adverse event
		Hypersensitivity Allergic contact dermatitis
Nervous system disorders	Common	Headache
	Uncommon	Dizziness
Eye disorders	Not known	Eye irritation
Cardiac disorders	Rare	Palpitations Heart rate increase (Tachycardia) Chest pain
Vascular disorders		
	Not known	Hypotension
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea
Gastrointestinal disorders	Uncommon Not known	Nausea Vomiting
Skin and subcutaneous tissue disorders	Common	Pruritus Rash
	Uncommon:	Hypertrichosis (unwanted non-scalp hair including facial hair growth in women).
	Not known	Temporary hair loss Hair colour changes Hair texture abnormal
General disorders and administration site conditions	Common	Weight increase
	Uncommon:	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 and erythema but can sometimes be more severe and include exfoliation, dermatitis, blistering, bleeding and ulceration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

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

Because of the concentration of minoxidil in Regaine, accidental ingestion has the potential of producing systemic effects related to the pharmacological action of the drug (2 g of Regaine contains 100 mg minoxidil; the maximum recommended adult dose for oral minoxidil administration in the treatment of hypertension). Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects associated with sodium and water retention, and tachycardia, hypotension and dizziness can also occur.

Treatment

Treatment of minoxidil overdosage should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatologicals, ATC code: D11AX01

Minoxidil stimulates hair growth and stabilise hair loss in persons with early and moderate stages of hereditary hair loss (alopecia androgenetica). This hair loss appears in men as a receding hairline and balding in the vertex area. The exact mechanism of action of minoxidil for topical treatment of alopecia is not fully understood, but minoxidil can stop the hair loss process and stimulates regrowth inandrogenetic alopecia by the following means:

§ Increasing the diameter of the hair shaft
§ Stimulating anagen growth
§ Prolonging the anagen stage
§ Stimulating anagen recovery from the telogen phase.

The efficacy of 5 % minoxidil foam has been assessed in a Phase 3 clinical trial conducted over a 16-week treatment period. In this study 5 % minoxidil foam was compared to the product vehicle without the minoxidil active ingredient.

The primary efficacy endpoints were a) mean change in non-vellus hair count within the target region between Baseline and Week 16, as determined by validated computer-assisted dot-mapping technique; and b) subject rating of treatment benefit via use of global photographs of the vertex region, assessed as an overall improvement from baseline, collected on a subject questionnaire.

The active treatment showed a statistically significant greater increase in hair count than the vehicle foam group (21.0 versus 4.3 hairs cm^2) at week 16. A clear difference between treatment groups was already evident at week 8, increasing at week 12 and again at week 16. The subject's rating of treatment benefit was statistically significantly better for the 5 % minoxidil foam treatment group than placebo (1.4 vs 0.5) at week 16.

Regaine Data: Mean change in non-vellus hair count in reference 1cm^2 area of scalp compared with baseline.

	Minoxidil 5% Foam (n=180)	Placebo (n=172)	Difference (p-value)
Baseline haircount	170.8	168.9	
	Mean charge from baseline	Mean change from baseline	
8 weeks	16.0	4.9	11.1 (<0.0001)
12 weeks	19.9	4.5	15.4 (<0.0001)
16 weeks	21.0	4.3	16.7 (<0.0001)

The statistically significant results obtained from the analysis of the primary efficacy endpoints were further confirmed in analysis of the secondary efficacy endpoints. These were a) expert panel review (EPR) of hair re-growth when comparing global photographs obtained at baseline with photographs obtained at Week 16 and b) percent change from baseline in non-vellus hair counts within a pre-specified area of clipped hair.

Several patterns of hair loss are commonly recognized and classified according to the Hamilton and Norwood scale, which is the standard classification for assessing hair loss development in men.

5.2 Pharmacokinetic properties

Regaine is thermolabile, melts at skin temperature and evaporates quickly.

Absorption
The systemic absorption of topically applied minoxidil from normal intact skin is low. 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 % foam formulation has been estimated in a pharmacokinetic study in subjects with androgenetic alopecia, which included 5 % topical solution as a comparator. This demonstrated that in men, the systemic absorption of minoxidil from twice daily application of 5 % minoxidil foam was about half of that observed with 5 % minoxidil solution. The mean steady state AUC (0-12 hr) and Cmax for 5 % minoxidil foam, 8.81 ng·hr/mL and 1.11 ng/mL, respectively, were both approximately 50 % of the 5 % solution. The median (range) time to maximum minoxidil concentration (Tmax) was 6.0 (0-12) hours for both for the 5 % foam, and the 5 % solution.

Distribution
The volume of distribution of minoxidil after intravenous administration has been estimated at 70 litres.

Biotransformation
Approximately 60% minoxidil absorbed after topical application is metabolised to minoxidil glucuronide, primarily in the liver.

Elimination
Minoxidil and its metabolites are excreted almost entirely in the urine, with a very minor degree of elimination via the faeces. Following cessation of dosing, approximately 95 % of topically applied minoxidil will be eliminated within four days.

5.3 Preclinical safety data

Preclinical data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or carcinogenic potential.

Teratogenicity
Animal reproduction toxicity studies in rats and rabbits have shown signs of maternal toxicity and a risk to the foetus at exposure levels that are very high compared to those intended for human exposure (from 19 to 570-fold human exposure). A low, albeit remote, risk of foetal harm is possible in humans.

Fertility
In rats, Minoxidil doses greater than 9 mg/kg (at least 25-fold human exposure) administered subcutaneously and oral dose equal to or greater than 3 mg/kg/day (at least 8 fold human exposure) were associated with reduced conception and implantation rates as well as reduction in the number of live pups.

There are no other non-clinical data of relevance to the prescriber which are additional to those already included elsewhere in the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol anhydrous

Purified Water
Butylhydroxytoluene (E321)
Lactic acid
Citric acid anhydrous
Glycerol
Cetyl alcohol
Stearyl Alcohol
Polysorbate 60
Propellant: Propane/n-Butane/Iso-butane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Danger extremely flammable aerosol: Pressurised container: May burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight and keep can in the outer packaging. Do not expose to temperatures exceeding 50°C.

6.5 Nature and contents of container

Polyamide imide lined aluminium pressurised container with a child-resistant polypropylene overcap, containing 60 gram (equivalent to 73 ml) of product. Packs contain either one or three cans.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Exposure of the container and contents to naked flame should be avoided during disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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