Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Regaine for Women 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 of 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 and 11.60 mg of cetyl alcohol.

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, female type (characteristic thinning of the hair in the parietal area) in women.

4.2 Posology and method of administration

Posology
Regaine for Women Extra Strength Scalp Foam is for external 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. A dose of 1 g (equivalent to the volume of half a capful) of Regaine for Women Extra Strength Scalp Foam should be applied on the affected areas on the top of the scalp once daily. The total dosage should not exceed 1 g.

Generally it will take a once-daily application for 12 weeks before evidence of hair growth can be expected. Users should discontinue use if there is no improvement seen after 24 weeks.
Continued use is necessary to maintain hair regrowth, or hair loss/hair thinning will begin again.

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

Paediatric population
Regaine for Women Extra Strength Scalp Foam 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 a non-absorbent surface like a clean dish or saucer. Within your hair thinning areas, make a center part to help maximize scalp exposure. Spread over the affected areas at the top of the head and gently massage the foam into the scalp from the back to front (forehead) direction.

Part your hair at least 2 more times on each side of the center part, and apply the remaining foam to each part as instructed above. Hands and the dish or saucer should be washed thoroughly after application to avoid accidental contact with eyes and mucous membranes.

To avoid that the foam rinses off, for approximately 4 hours after application the scalp should not be exposed to water.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Roquinna should be used when the scalp is normal and healthy. i.e. it is not red or inflamed or not infected or irritated or painful.

Before the start of treatment with 5% minoxidil topical foamthe patient should be thoroughly examined and medical history should be evaluated. Endocrinological disorders, underlying systemic disorders or malnutrition should be ruled out and if applicable, a specific therapy should be implemented.

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

Patients with known cardiovascular disease, cardiac arrhythmia or hypertension should consult a physician before using Roquinna.

The patient should stop using Roquinna and see a doctor if hypotension is detected (see section 4.8) 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.

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

When treatment with minoxidil is stopped, shedding of the hairs will occur again.

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 Roquinna and consult their doctor.

Users should be aware that, whilst extensive use of Roquinna 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 to systemic effects.

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

Roquinna 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.

Roquinna 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).

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

Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp.

4.5 Interaction with other medicinal products and other forms of interaction

Regaine for Women Extra Strength Scalp Foam should not be used concomitantly with other medications (i.e. corticosteroids, tretinoin, dithranol) 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; betamethasone dipropionate increases local tissue concentrations of minoxidil and decreases systemic minoxidil absorption.

4.6 Fertility, pregnancy and lactation

Fertility
There are no adequate and well controlled studies in relation with women fertility.
Studies in animals 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.There is a low risk of foetal harm (see Section 5.3, Preclinical Safety Data).

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, Preclinical Safety Data). There is a low risk of foetal harm (see Section 5.3, Preclinical Safety Data).

Breast-feeding
Systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.
Regaine for Women Extra Strength Scalp Foam is not recommended during pregnancy or lactation nor to women of childbearing potential not using contraception.

4.7 Effects on ability to drive and use machines

Regaine for Women Extra Strength Scalp Foam may cause dizziness or hypotension (see Section 4.8). If patients are affected they should not drive or operate machinery.

4.8 Undesirable effects

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).

Adverse events data from one placebo-controlled study of 5 % minoxidil topical foam once-daily in women, one placebo-controlled clinical trial with 5% minoxidil foam in men, seven placebo-controlled clinical trials with males and females treated with minoxidil solution (2% and 5%),as well as post-marketing experience with all minoxidil formulations (including 2 % solution, 5 % solution and 5 % foam in men and women) are included in the below table:

System Organ Class	Frequency	Reported adverse reactions
Immune System Disorders	Not known	Allergic reactions including angioedema (with symptoms such as e.g. oedema of lips, mouth, tongue and pharynx, and oropharynx) Hypersensitivity (including face oedema, generalised erythema, pruritus generalised and throat tightness) Contact dermatitis
Nervous system disorders	Very Common	Headache
	Uncommon	Dizziness

System Organ Class	Frequency	Reported adverse reactions
Eye disorders	Not known	Eye irritation
Cardiac disorders	Not known	Palpitations Tachycardia
Vascular disorders	Common	Hypertension
	Not known	Hypotension
Respiratory, thoracic and mediastinal disorders	Common	Dyspnoea
Gastrointestinal disorders	Uncommon	Nausea
	Not known	Vomiting
Skin and subcutaneous tissue disorders	Common	Dermatitis, dermatitis acneiform, rash, hypertricosis, pruritus Scalp irritation like stinging/burning, pruritus, dryness/scaling, folliculitis. Facial hypertrichosis
	Not Known	Temporary hair loss Hair colour changes Hair texture abnormal Application site reactions which also may involve the ears and face, such as pruritus, skin irritation, pain, rash, oedema, dry skin and erythema up to exfoliation, dermatitis, blistering, bleeding and ulceration.
General disorders and administration site conditions	Common	Oedema peripheral
	Rare	Chest pain
Investigations	Common	Weight increase

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 for Women Extra Strength Scalp Foam are applied to larger surface areas of the body or areas other than the scalp.

Increased systemic absorption may occur if this product is applied to an area with decreased integrity of the epidermal barrier caused by trauma, inflammation, or disease process in the skin.

Because of the concentration of minoxidil in Regaine for Women Extra Strength Scalp Foam, accidental ingestion has the potential of producing systemic effects related to the pharmacological action of the drug (1 g of Regaine for Women Extra Strength Scalp Foam contains 50 mg minoxidil; the half 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 could 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

Topical minoxidil stimulates hair growth in males and females with androgenetic alopecia. The mechanism by which minoxidil stimulates hair growth is not fully understood, but some effects of minoxidil include increasing the diameter of the hair shaft, stimulation of anagen growth, and prolongation of the anagen growth phase, and stimulation of transition of hair follicles from the resting phase (telogen) to the growth phase (anagen).

Clinical Studies

The efficacy of minoxidil 5 % foam for the treatment of androgenic alopecia of the female type has been assessed in two phase-3 clinical trials in women.

In a randomised, active-controlled double-blind multicentre study, minoxidil 5 % foam applied once daily was compared to minoxidil 2% solution applied twice daily, each for 52 weeks. Primary efficacy was assessed by the change from baseline in target area hair count (TAHC), as measured by macro photography at Week 24.

Change from baseline in TAHC (hairs/cm^2)		
	Minoxidil 5% foam (n=161)	Minoxidil 2% solution (n=161)
Week 24	23.7 (15.8%)	23.8 (16.2%)
Week 52	18.1 (12.6%	19.4 (13.6%)

In the second study, a randomised, placebo-controlled, double-blind, multi-centre study, minoxidil 5% foam applied once a day was compared to the foam vehicle, containing no active substance. Each was applied once daily, for 24 weeks. Primary efficacy was assessed by the change from baseline in TAHC, as measured by macro photography at baseline and Week 24, and subject assessment of scalp coverage from global photographs, as measured by the change from baseline at Week 24 on a 7-point scale.

	Change from baseline in TAHC (hairs/cm^2)		Subject Self-Assessment of Scalp Coverage (from baseline)	
	Vehicle (n=197)	Minoxidil 5% foam (n=200)	Vehicle (n=183)	Minoxidil 5% foam (n=180)
Week 24	4.0 (2.7%)	13.5 (9.4%; p<0.0001)	+0.06	+0.74 (p<0.0001)

The maximum effect was observed at week 12.

The two efficacy studies demonstrate that minoxidil 5 % foam applied once a day provides benefits to women with androgenetic alopecia, female type, after 12 to 24 weeks of treatment, including promotion of hair regrowth, and moderate improvement in scalp coverage and increase in hair density.
On average the maximum effect was observed at week 12 and week 24. A treatment after week 12 and 24, respectively, was not related to a further increase of the effect.

5.2 Pharmacokinetic properties

The foam is thermolabile, melts at skin temperature and evaporates quickly.

Absorption
The systemic absorption of topically applied minoxidil from normal intact skin is low and ranges between 1% and 2% of the total applied dose.

In a pharmacokinetic study the systemic absorption from the 5% minoxidil topical foam wasevaluated separately in men and women and was compared with the systemic absorption from a minoxidil topical solution (5% or 2%). In male subjects, the systemic absorption of twice-daily 5 % minoxidil topical foam was about half of that observed with twice-daily 5 % minoxidil topical solution. The mean AUC (0-12 hr) and Cmax were 8.81 ng·hr/mL and 1.11 ng/mL, respectively, for the 5 % foam and 18.71 ng·hr/mL and 2.13 ng/mL, respectively, for the 5 % solution. The time to maximum minoxidil concentration (Tmax) for the 5 % foam, 5.42 hr, was similar to Tmax for the 5 % solution, 5.79 hr. In women, the minoxidil exposure was approximately similar after once-daily administration of a 5 % minoxidil topical foam and twice-daily administration of a 2 % minoxidil topical solution. The mean AUC (0-24 hr) and Cmax after once-daily administration of the 5% topical foam was 12.0 ng·hr/mL and 1.25 ng/ml, respectively.

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.

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

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 seen 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.

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). There is a low risk of foetal harm in humans.

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. Keep the can in the outer carton in order to protect from sunlight. 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 two cans.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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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