Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Regaine for Women Regular Strength 2% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each milliltre of solution contains 20 mg minoxidil equivalent to 2% w/v minoxidil.

Excipients: Propylene glycol (E1520) 208 mg/ml and ethanol 454.46 mg/ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.
Clear, colourless to light-yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Slowing of hair loss in alopecia androgenetica.

Regrowth of hair in alopecia androgenetica.

4.2 Posology and method of administration

Posology

Adults aged between 18 and 65 years of age:

A dose of 1 ml should be applied to the total affected areas of the scalp twice daily (once in the morning and once in the evening. The total daily dose should not exceed 2 ml.

Duration of use

It may take at least 2 to 4 months of twice a day treatment before results are seen. Onset and degree of hair growth may be variable among patients.

Continuous twice-daily usage is necessary to maintain the results of treatment.
Relapse to pre-treatment appearance following discontinuation of medication has been reported to occur within 3-4 months.

In the absence of any clear response in women, the treatment should be discontinued after 8 months.

Method of administration

For topical use only.

The hair and scalp should be thoroughly dry prior to topical application.

Wash hands thoroughly after application.

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.

4.3 Contraindications

Regaine Regular Strength is contra-indicated:

- in users with a history of hypersensitivity to minoxidil or any of the excipients.
- in users with treated or untreated hypertension
- in users with any scalp abnormality (including psoriasis and sunburn)
- in users with a shaved scalp
- if occlusive dressings or other topical medical preparations are being used.

4.4 Special warnings and precautions for use

The safety and efficacy of the product in patients aged under 18 or over 65 is unknown.

Regaine should only be used on a normal healthy scalp. Do not use if scalp is inflamed, infected, rritated or painful.

Regaine should not be used concurrently with any other medicines on the scalp.

Regaine is only indicated for the treatment of alopecia androgenetica and should not be used in other type of hair loss for example 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.

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

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.

Regaine for Women Regular Strength is for external use only. Do not apply to areas of the body other than the scalp.

Hands should be washed thoroughly after applying the solution. Inhalation of the spray mist should be avoided.

Regaine for Women Regular Strength contains 454.46 mg of alcohol (ethanol) in each 1ml. It may cause burning sensation on damaged skin. In the event of accidental contact with the eye or other sensitive surface such as abraded skin or mucous membranes, the area should be bathed with large amounts of cool tap water.
Regaine for Women Regular Strength contains 208 mg of Propylene glycol in each 1 ml. It may cause skin irritation.

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

Some consumers reported increased hair shedding upon initiation of therapy with Regaine for Women Regular Strength. This is most likely due to minoxidil's action of shifting hairs from the resting telogen phase to the growing anagen phase (old hairs fall out as new hairs grow in their place). This temporary increase in hair shedding generally occurs two to six weeks after beginning treatment and subsides within a couple of weeks. If shedding persists (>2 weeks), users should stop using Regaine for Women Regular Strength and consult their doctor.

Users should be aware that, whilst extensive use of Regaine for Women Regular Strength 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.

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.

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

The solution is flammable and exposure of the container and contents to naked flames, lit cigarette or some devices (e.g. hairdryers) should be avoided during use, storage and disposal (see section 6.6).

4.5 Interaction with other medicinal products and other forms of interaction

Topical minoxidil should not be used concurrently with any other medications on the scalp.

Pharmacokinetic drug interaction studies in humans revealed percutaneous minoxidil absorption is enhanced by tretinoin and anthralin as a result of increased stratum corneum permeability; betmethasone dipropionate increases local tissue concentrations of minoxidil and decreases systemic minoxidil absorption.

Guanethidine has been reported to interact with oral formulations of minoxidil resulting in rapid and pronounced lowering of blood pressure.

4.6 Fertility, pregnancy and lactation

Topical minoxidil should not be used during pregnancy and lactation.

Fertility
There are no adequate and well controlled studies relating to female fertility.

Studies in animals have shown fertility toxicity - reduced conception and implantation rates as well as a 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 humans is unknown.

Pregnancy
There are no adequate and well controlled studies in pregnant women. Animal studies have shown a risk to the foetus at exposure levels that are very high compared to those intended for human exposure. There is potentially a risk of foetal harm in humans (see section 5.3, Preclinical safety data)

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

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

In placebo controlled trials, the overall frequency of adverse events in females in all body system categories was approximately five times that of males.

Several thousand patients have used topical minoxidil in clinical trials where a comparison with an inactive solution was made. Dermatological reactions (e.g. irritation, itching) occurred in patients using both solutions. This has been explained by the presence of propylene glycol in both the active and inactive solution.

The safety of topical minoxidil from clinical trial data is based on data from 7 placebo-controlled randomised clinical trials in adults evaluating either 2% or 5% minoxidil solution, and two placebo-controlled randomised 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 below by System Organ Class (SOC).

The frequencies are provided according to the following convention:
Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Body System (SOC)	***Frequency***	***Adverse Drug Reaction (Preferred Term)***
Immune system disorders	*Not known*	*Allergic contact dermatitis*
	Not known	*Allergic reactions including angioedema* *Hypersensitivity*
Nervous system disorders	*Very common*	*Headache*
	Uncommon	*Dizziness*
Eye disorders	*Not known*	*Eye irritation (including eye pruritus)*
Cardiac disorders	*Rare*	*Chest pain* *Heart rate increased (Tachycardia)* *Palpitations*
Vascular disorders	*Not known*	*Hypotension*
Respiratory, thoracic and mediastinal disorders	*Common*	*Dyspnoea*
Gastrointestinal disorders	*Uncommon*	*Nausea*
	Not known	*Vomiting*
Skin and subcutaneous tissue disorders	*Common*	*Dermatitis (including atopic and seborrhoeic dermatitis)* *Dermatitis acneiform* *Hypertrichosis (unwanted non-scalp hair including facial hair growth in women)* *Pruritus* *Rash (including rash pruritic, pustular, papular, generalised vestibular and macular)*
	Not known	*Hair colour changes* *Hair texture abnormal* *Temporary hair loss*
General disorders and administration site conditions	*Common*	*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)*
Investigations	*Common*	*Weight increased**

** This adverse event was identified during clinical trials with Minoxidil Foam*

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

Signs and symptoms
Increased systemic absorption of minoxidil may potentially occur if higher-than-recommended doses are applied to larger surface areas of the body or areas other than the scalp which therefore may lead to adverse events.

There is no evidence that topically applied minoxidil is absorbed in sufficient quantity to cause systemic effects. When used as directed, overdose is unlikely.

Overdose due to oral administration or excessive systemic exposure of minoxidil exaggerates its cardiovascular effects and may present as hypotension, tachycardia and lethargy.

Because of the high concentration of minoxidil in Regaine for Women Regular Strength (5ml of 2% solution contains the maximum recommended adult dose (100mg) of minoxidil used orally in the treatment of hypertension), accidental ingestion of Regaine for Women Regular Strength has the potential of producing systemic effects. Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects such as oedema, tachycardia, faintness or dizziness.

If this product is applied to an area of decreased integrity of the epidermal barrier caused by trauma, inflammation, or disease process in the skin, there is a potential for a systemic overdose effect.

The following very rare adverse events may occur due to the systemic effects of minoxidil;

Very Rare: (< 1/10,000)
Cardiovascular disorders: Heart rate increased, hypotension
General Disorders: Fluid retention resulting in weight increase
Nervous System Disorders: Dizziness

Treatment
Treatment of minoxidil overdosage should be symptomatic and supportive. Fluid retention can be managed with appropriate diuretic therapy. Clinically significant tachycardia can be controlled by administration of a beta-adrenergic blocking agent.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Regaine for Women Regular Strength stimulates hair growth in individuals with androgenetic alopecia in males (expressed as baldness of the vertex of the scalp) and females (expressed as diffuse hair loss or thinning of the scalp).

The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can stabilise and reverse the hair loss process of androgenetic alopecia.

5.2 Pharmacokinetic properties

The failure to detect evidence of systemic effects during treatment with Regaine for Women Regular Strength reflects the poor absorption of topical minoxidil, which averages about 1.4% (range 0.3-4.5%) of the total applied dose from normal intact skin. Absorption is about 2% when applied topically to shaved scalps of hypertensive patients. Increasing the amount of drug applied or increasing the frequency of application of Regaine for Women Regular Strength also results in increased absorption. The use of Regaine for Women Regular Strength in conjunction with occlusion (plastic dressings), application to sunburn areas, and increasing the surface area of application has minimal to no effect on the absorption of topical minoxidil. Results of extensive pharmacokinetic studies indicate that the three major factors by which topical minoxidil absorption are increased by are: Increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum.

Serum minoxidil levels and systemic effects resulting from administration of Regaine for Women Regular Strength are governed by the drug's absorption rate through the skin. Following cessation of topical dosing of Regaine for Women Regular Strength, approximately 95% of the systemically absorbed drug is eliminated within 4 days. Minoxidil and its metabolites are excreted principally in the urine.

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.

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

Carcinogenicity
A high incidence of hormone-mediated tumours was observed in mice and rats. These tumours 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 tumour promotion by minoxidil does not represent a carcinogenic risk to humans.

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 use.

Fertility
Minoxidil doses greater than 9 mg/kg (at least 25-fold human exposure) administered subcutaneously in rats were associated with reduced conception and implantation rates as well as reduction in the number of live pups.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol (E1520)
Ethanol (96 per cent)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

This medicinal product is flammable. Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottle with spray / pump applicator containing parts made from polypropylene and low-density polyethylene (LDPE). Contents are 60 ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The solution is flammable and exposure of the container and contents to naked flames, lit cigarette or some devices (e.g. hairdryers) should be avoided during use, storage and disposal.

7 MARKETING AUTHORISATION HOLDER

JNTL Consumer Health I (Ireland) Limited
Office 5, 6 And 7
Block 5
High Street
Tallaght
Dublin 24
D24 YK8N
Ireland

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