AUSTRALIANPRODUCT INFORMATION

MEN'S REGAINE EXTRA STRENGTH application, MEN'S REGAINE EXTRA STRENGTH FOAM, WOMEN'S REGAINE REGULAR STRENGTH application, WOMEN'S REGAINE foam – (MINOXIDIL)

1 NAME OF THE MEDICINE

Minoxidil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

- MEN'S REGAINE EXTRA STRENGTH
- MEN'S REGAINE EXTRA STRENGTH FOAM
- WOMEN'S REGAINE

Active ingredient: minoxidil 50 mg/mL (5%)
Excipients with known effect: alcohol

- WOMEN'S REGAINE REGULAR STRENGTH

Active ingredient: minoxidil 20 mg/mL (2%)
Excipients with known effect: alcohol

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

- MEN'S REGAINE EXTRA STRENGTH
- WOMEN'S REGAINE REGULAR STRENGTH

Clear, colourless to light yellow liquid

- MEN'S REGAINE EXTRA STRENGTH FOAM
- WOMEN'S REGAINE

White to yellowish, creamy foam

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

REGAINE Topical Application, Extra Strength Topical Application and Extra Strength Foam are indicated for the treatment of androgenetic alopecia (common baldness) in healthy adult males and females.

4.2 DOSE AND METHOD OF ADMINISTRATION

FOR EXTERNAL USE ONLY.

Use REGAINE Topical Application, Extra Strength Topical Application and Extra Strength Foam only as directed. Do not apply REGAINE® to any area of the body other than the scalp. Make sure the scalp and hair are thoroughly dry and that the skin is healthy and intact.

Do not use a hairdryer to speed the drying of REGAINE®, because blowing air on the scalp may decrease the effectiveness of REGAINE®. REGAINE® must remain in contact with the scalp for several hours (up to 4 hours).

At least four months of twice daily applications of REGAINE® (Once a day application for Women's REGAINE®) are generally required before evidence of hair regrowth can be expected. Onset and degree may be variable among patients.

Note: Following discontinuation of medication, relapse to pretreatment appearance has been reported to occur within 3-4 months.

Dose: Topical Application (solution)
1mL REGAINE® should be applied twice per day to the scalp, beginning at the centre of the affected area. This dose should be used regardless of the size of the affected area. The total daily dose should not exceed 2 mL. After applying REGAINE®, wash hands thoroughly.

Directions For Use of Solution:
Dropper
This applicator is designed to deliver a measured amount (1 mL or 1 dose) of solution.

1 Unscrew the child-resistant cap.
2 Hold the bottle upright. Whilst ensuring that the dropper is immersed in the solution, squeeze the bulb to fill the dropper to the black line. The applicator now contains one full dose (1 mL) of REGAINE® and is ready for use.
3 Aim the dropper to the area of the scalp you wish to treat, lifting any hair out of the way with your fingers or comb. Gently squeeze the dropper bulb and apply the solution dropwise.
4 Massage the solution into the scalp gently with your fingers. Wash your hands after you have finished massaging the solution into your scalp.
5 Replace the child-resistant dropper by screwing the dropper firmly onto the bottle.

Dose: Topical Foam
Men's REGAINE® Extra Strength topical foam:
REGAINE® foam should be applied sparingly twice per day to the scalp, beginning at the centre of the affected area. Up to half a capful may be used, but men with a small area of hair loss may need less. After applying REGAINE®, wash hands thoroughly.

Women's REGAINE® topical foam:
REGAINE® foam should be applied sparingly once a day to the scalp, beginning at the centre of the affected area. After applying REGAINE®, wash hands thoroughly.

Directions For Use of Foam:
1. To open container: Match arrow on can ring with line on cap. Pull off cap.
2. Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
3. The foam may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam)
4. Hold the can upside down and press nozzle to dispense the topical foam

product into the palm of your hand. The total amount of foam applied should not exceed half a capful.
5. Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
6. After each use, close the container to make child resistant by snapping the cap back on to the can.

4.3 CONTRADINDICATIONS

REGAINE topical foam and topical solution are contraindicated in patients with a history of hypersensitivity to minoxidil, or ethanol.

REGAINE topical solution is also contraindicated in patients with a history of hypersensitivity to propylene glycol.

REGAINE® is also contraindicated in pregnant or nursing women.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Accidental ingestion of REGAINE could lead to serious adverse effects.

Before starting a patient on REGAINE, the physician or pharmacist should ascertain that the patient has a healthy, normal scalp. It should not be applied to inflamed, infected, irritated or painful scalp skin.

Although extensive use of topical minoxidil has not revealed evidence that enough 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 a systemic effect and physicians and patients need to be aware of this.

REGAINE is recommended for use only in healthy adults with normal cardiovascular status. The safety of REGAINE is unknown in patients with cerebrovascular disease, or cardiovascular disease (including ischaemic heart disease, cardiac arrhythmias or congestive heart failure). Patients with a history of underlying heart disease should be aware that adverse effects in them might be especially serious (see also Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)).

The patient should stop using REGAINE and see a physician if hypotension is detected or if experiencing chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness or irritation of the scalp. If affected by dizziness or hypotension do not drive or operate machinery.

In the event of severe dermatological reactions patients should discontinue use of REGAINE and contact their physician or pharmacist.

REGAINE contains an alcohol base which will cause burning, and irritation of the eye on contact. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), the area should be bathed with copious amounts of cool tap water.

The effects of REGAINE in patients with concomitant skin diseases, or in those using topical corticosteroids or other dermatological preparations, are unknown. There is a possibility that an increase in bioavailability of topically administered minoxidil may occur in the presence of inflammatory conditions of the scalp and such situations are to be avoided. Topical minoxidil should not be used concurrently with any other medications on the scalp.

If a patient wishes to wear any form of protective headgear, they should be instructed to allow 1 hour to elapse after using REGAINE before covering the head. Some patients have experienced changes in hair colour and/or texture with use of REGAINE.

Topical minoxidil therapy should be stopped if hair regrowth is not evident after 6 months of treatment.

Topical minoxidil should not be used if hair loss is patchy and/or sudden or if the reason for the hair loss is unknown. Using more than the recommended dose or more often will not improve results. Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again. A temporary increase in hair shedding may occur within the first 2-6 weeks of treatment. Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp. Contact between children and minoxidil application sites should be avoided.

Products labelled for women*:* Topical minoxidil should not be used if hair loss is due to childbirth.

Use in the elderly

Safety and efficacy of REGAINE in patients over 65 years of age have not been established.

Paediatric use

Safety and efficacy of REGAINE in patients under 18 years of age have not been established.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

There are currently no known drug interactions associated with the use of REGAINE. Although it has not been clinically demonstrated, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension in patients currently taking peripheral vasodilators. *In vitro* studies have shown that paracetamol and diethylcarbamazine may inhibit the stimulation of hair growth by minoxidil.

The use of REGAINE concurrently with cutaneously used drugs which alter the stratum corneum barrier, e.g. tretinoin and anthralin/dithranol is not recommended due to the possibility of increased absorption of cutaneously used minoxidil and consequently, increased potential for adverse drug reactions.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

In fertility studies in rats, minoxidil decreased live litter size at oral doses of 3-10 mg/kg/day and at 80 mg/kg/day SC.

Use in pregnancy: Category C

Oral administration of minoxidil has been associated with hypertrichosis in the newborn infant following exposure in utero. The safety of topical minoxidil in pregnancy has not been established, therefore REGAINE should not be used by pregnant women.

Subcutaneous administration of minoxidil to pregnant rats during organogenesis caused foetal deaths, decreased foetal weight, and increased incidences of external, visceral and skeletal abnormalities. These effects were observed in two strains of rats at doses of 120 to 160 mg/kg/day, and were associated with mild to moderate maternal toxicity. No development effects were observed at non-maternotoxic dose levels. No teratogenic effects were observed in rabbits at oral doses up to 10 mg/kg/day or at subcutaneous doses up to 49 mg/kg/day. In a peri/postnatal study in rats, subcutaneous administration of minoxidil at 80 mg/kg/day caused an increase in gestation length, prolonged parturition, an increased incidence of stillbirths and reduced birth weight.

Use in lactation

Systemically-absorbed minoxidil is secreted in human milk. REGAINE should not be used by nursing women.

Subcutaneous administration of minoxidil at 80 mg/kg/day to lactating rats suppressed postnatal growth and increased postnatal mortality of the offspring. These effects may have been due to interference with nursing behaviour rather than to ingestion of drug-related material by the offspring.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

May cause dizziness or hypotension (see Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). If affected do not drive or operate machinery.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The most frequently encountered adverse effect in clinical trials with REGAINE® was mild dermatitis of the scalp. The dermatological events were of a similar type and severity in the 2% and 5% groups, but the incidence was greater in the 5% group.

Most frequently reported adverse reactions with 2% and 5% topical minoxidil in commercial marketing experience are dermatological reactions and include: local erythema, itching and dry skin/scalp flaking. 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).

Other adverse reactions that have been reported very rarely (<0.01%) include irritant dermatitis (redness/erythema, scaling/rash scaly and burning), non-specific allergic

reactions, hives, hypersensitivity, allergic contact dermatitis, allergic rhinitis, facial swelling, folliculitis, alopecia, hypertrichosis, hair abnormalities, seborrhoea, shortness of breath, headache, neuritis, dizziness/lightheadedness, syncope, vertigo, oedema, chest pain, blood pressure changes (decreased and increased blood pressure, hypotension, hypertension), palpitations and pulse rate changes, rapid heart beat/tachycardia.

Rare cases of hypertrichosis (unwanted non-scalp hair including facial hair growth in women) have been reported.

Clinical Trial Data

The safety of topical minoxidil from clinical trial data is based on data from 7 placebo-controlled randomized clinical trials in adults evaluating either 2% or 5% minoxidil solution, and two placebo-controlled randomized clinical trials in adults evaluating a 5% foam formulation for the treatment of androgenetic alopecia in males and females.

Table 1 includes adverse drug reactions from the 7 solution studies and Table 2 includes adverse events from the 2 foam studies where greater than one event was reported, and the incidence was greater than placebo and in 1% of patient or more.

Adverse drug reactions identified in clinical trials with topical minoxidil are included in Tables 1 and 2; the frequencies in the following tables are provided according to the following convention:

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

Table 1: ADRs Reported by ≥1% of Topical Minoxidil-Treated Adult Subjects in Randomized Placebo-Controlled Clinical Trials with the 2% or 5% Solution Formulation

System Organ Class **Preferred Term**	**Topical Minoxidil** (N=1197) % (frequency)	**Placebo** (N=365) % (frequency)
General disorders and administration site conditions *Oedema peripheral*	3.3 (common)	1.6
Nervous System Disorders *Headache*	15.0 (Very Common)	12.6
Respiratory, thoracic and mediastinal disorders *Dyspnoea*	1.2 (Common)	1.1

Skin and subcutaneous tissue disorders		
Dermatitis	1.5 (Common)	1.1
Dermatitis acneiform	1.6 (Common)	1.4
Hypertrichosis	1.8 (Common)	0.3
Pruritus	3.6 (Common)	1.9
Rash	1.7 (Common)	0.8

Table 2: ADRs Reported by ≥1% of Topical Minoxidil-Treated Adult Subjects in Randomized Placebo-Controlled Clinical Trials with the 5% Foam Formulation

System Organ Class **Preferred Term**	**Topical Minoxidil** (N=383) % (frequency)	**Placebo** (N=373) % (frequency)
Investigations		
Weight increased	4.4 (common)	3.8
Nervous System Disorders		
Headache	5.0 (Common)	3.8
Skin and subcutaneous tissue disorders		
Pruritus	1.8 (Common)	1.3
Rash	1.8 (Common)	0.5

Post-marketing data

Additional adverse drug reactions (ADRs) identified during post-marketing experience with minoxidil are included in Table 3.

Table 3: Adverse Drug Reactions Identified During Post-Marketing Experience with Minoxidil by Frequency Category Estimated from Spontaneous Reporting Rates*

SOC	**Adverse Event Preferred Term**
Immune System Disorders	
Very rare	*Angioedema (the manifestations of angioedema may include the following: Lip oedema, Oedema mouth, Oropharyngeal swelling, Pharyngeal oedema, and Tongue oedema)*
Very rare	*Hypersensitivity (the manifestations of hypersensitivity reactions may include the following: Face oedema, Generalised erythema, Pruritus generalised, and Throat tightness)*
Very rare	*Dermatitis contact*
Psychiatric Disorders	
Very rare	*Depressed mood*

Nervous System Disorders Very rare	 *Dizziness*
Eye Disorders Very rare	 *Eye irritation*
Cardiac Disorders Very rare Very rare	 *Tachycardia* *Palpitations*
Vascular Disorders Very rare	 *Hypotension*
Gastrointestinal Disorders Very rare Very rare	 *Nausea* *Vomiting*
Skin and Subcutaneous Tissue Disorders Very rare Very rare Very rare Very rare	 *Application site reaction (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)* *Alopecia* *Hair colour changes* *Hair texture abnormal*
General Disorders and Administration Site Conditions Very rare	 *Chest pain*

*** Patient exposure was estimated by calculation from sales data from IMS MIDAS™**

Reporting Suspected Adverse Events

Reporting suspected adverse reactions after registration 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 at: https://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Due to the high concentration of minoxidil in REGAINE, accidental ingestion may produce systemic effects related to the vasodilatory action of minoxidil. Signs and symptoms of drug overdosage would most likely be cardiovascular effects associated with fluid retention, tachycardia or lowered blood pressure. Fluid retention can be managed with appropriate diuretic therapy. Tachycardia can be controlled by administration of a beta-adrenergic blocking agent. Symptomatic hypotension should be treated by intravenous administration of normal saline. Sympathomimetic drugs, such as noradrenaline and adrenaline should be avoided because of their excessive cardiac stimulating activity.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

When applied topically, REGAINE has been shown to stimulate hair growth in males and females with alopecia androgenetica; however, the exact mechanism of action of REGAINE in the treatment of alopecia androgenetica is not known. The regrowth can be observed after approximately 4 or more months of use and is variable among patients. Upon discontinuation of treatment with REGAINE®, new hair growth stops and restoration of pretreatment appearance may occur within 3-4 months.

Topical application of REGAINE showed no systemic effects related to absorption of minoxidil when tested in controlled clinical trials in both normotensive and untreated hypertensive patients.

Minoxidil administered orally for the treatment of hypertension has a direct peripheral vasodilator effect which reduces elevated systolic and diastolic blood pressure by decreasing peripheral vascular resistance. Reduction of peripheral arteriolar resistance and the associated fall in blood pressure induces sympathetic, vagal inhibitory, and renal homeostatic mechanisms, including an increase in renin secretion, which lead to increased heart rate and cardiac output, and salt and water retention. Minoxidil does not interfere with vasomotor reflexes and therefore does not produce orthostatic hypotension. In experimental animals, the drug does not enter the central nervous system (CNS) in significant amounts.

Clinical trials

In 2,326 adults with early male pattern baldness who applied 1 mL of 2% TMS (transdermal minoxidil solution) on the scalp twice daily for 12 months, cosmetically acceptable hair growth was observed in only a small % of individuals. Dense hair growth occurred in only 8% of individuals. Moderate hair growth was observed in a further 30% of subjects.

Two studies in healthy males aged 18-50 years with androgenetic alopecia showed statistically significant differences favouring 5% over 2% TMS with regard to non-vellus hair counts. Compared to mean baseline counts of 103-106/cm2, at the end of 32 weeks treatment mean increases in non-vellus hair counts were 39/cm2 in subjects who received 5% TMS (N=163), 30/cm2 in subjects who received 2% TMS (N=79), and 5/cm2 in subjects who received placebo (N=79). In the other study, compared to mean baseline counts of 144-152 /cm2, at the end of 48 weeks treatment mean increases in non-vellus hair counts were 19/cm2 in subjects who received 5% TMS (N=137), 13/cm2 in subjects who received 2% TMS (N=139), and 4/cm2 in subjects who received placebo (N=70).

Two studies in healthy females aged 18 to 50 years with androgenetic alopecia showed statistically significant differences favouring 5% over placebo, but not over 2% TMS with regard to non-vellus hair counts. Compared to mean baseline counts of 178-185 /cm2, at the end of 36 weeks treatment mean increases in non-vellus hair counts were 18/cm2 in subjects who received 5% TMS (N=64), 15/cm2 in subjects who received 2% TMS (N=74) and 3/cm2 in subjects who received placebo (N=40). In the other study, compared to mean baseline counts of 138-150/cm2, at the end of 48 weeks treatment mean increases in non-vellus hair counts were 25/cm2 in subjects who received 5% TMS (N=97), 21/cm2 in subjects who received 2% TMS (N=106) and 9/cm2 in subjects who received placebo (N=50).

Examination of efficacy data based on hair weight measurements demonstrated an overall clinical benefit of 5% TMS and 2% TMS in stimulating hair growth.
Additionally, this study strongly demonstrated the stabilisation of hair loss over the 2 year treatment period.

The efficacy and safety of REGAINE Extra Strength Foam was evaluated in a 16-week, double-blind, placebo-controlled study in males with androgenetic alopecia. Increase in mean non vellous hair count after 8, 12 and 16 weeks in the target area were significantly greater ($p< 0.0001$) for the REGAINE® Extra Strength Foam treated subjects (n=180; intent-to-treat population) compared to the placebo foam treated subjects (n=172; intent-to-treat population). Analysis of subject ratings of treatment after 16 weeks of treatment were also statistically better ($p<0.0001$) for the REGAINE® Extra Strength Foam treated subjects compared to the placebo foam treated subjects. These results were confirmed by subsequent analysis based on the per protocol population.

Overall the study treatments were well tolerated and the incidence of adverse events with 5% minoxidil foam was similar to that with placebo foam.

Two studies were performed to assess the efficacy and safety of MTF (minoxidil topical foam) when applied once a day (OD) in female subjects with female pattern hair loss. In one study 5% MTF OD was compared to a foam vehicle containing no active product. Each was applied once daily, for 24 weeks. After 24 weeks of treatment, the 5% MTF OD group (n=200) re-grew 13.4 hairs/cm2 and the foam vehicle group (n=197) re-grew 4.3 hairs/cm2, a treatment difference of 9.1 hairs/cm2 ($p<0.0001$). After 24 weeks of treatment, subjects in the 5% MTF OD group observed improved scalp coverage from baseline. The adjusted mean scalp coverage scores were 0.75 versus 0.06 for the 5% MTF OD and the foam vehicle groups, respectively, a significant treatment difference of 0.69 ($p<0.0001$). In the other study, the efficacy of 5% MTF OD was compared to 2% TMS BID (twice daily). Compared to mean baseline counts of 169.7/cm2, after 24 weeks treatment mean increases in non-vellus hair counts were 23.9/cm2 in subjects who received 5% MTF OD (n=161). 5% MTF OD was concluded to be at least as effective as 2% MTS BID. Overall safety analyses have shown 5% MTF OD to be well tolerated in healthy subjects and in women with female pattern hair loss (FPHL). The safety profile of 5% MTF in females was generally similar to that observed in clinical trials of 5% MTF BID in males.

5.2 PHARMACOKINETIC PROPERTIES

Following topical application, minoxidil is poorly absorbed from normal intact skin. Of the total applied dose an average of 1.7% (range 0.3-4.5%) of the topical solution reaches the systemic circulation. The relative absorption of the topical foam is approximately 50% of a similar dose of topical solution. In contrast, minoxidil is almost completely absorbed from the gastrointestinal tract following oral administration of minoxidil tablets. Following cessation of topical dosing of REGAINE®, approximately 95% of systemically absorbed minoxidil is eliminated within 4 days. The effects of concomitant dermal diseases on absorption are unknown.
The metabolic biotransformation of minoxidil absorbed following topical application has not been fully determined. But the active form of the drug appears to be a sulfated metabolite, minoxidil sulfate. Orally administered minoxidil is metabolised predominantly by conjugation with glucuronic acid at the N-oxide position in the

pyrimidine ring but also by conversion to more polar products. Minoxidil does not bind to plasma proteins and its renal clearance corresponds to the glomerular filtration rate. Minoxidil does not cross the blood brain barrier. Minoxidil and its metabolites are haemodialysable and are excreted principally in the urine.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Genetic toxicology studies showed that minoxidil does not cause gene mutation in bacterial cells, but gene mutation studies in mammalian cells have not been reported. Minoxidil had weak clastogenic activity in a cytogenetics assay in Chinese hamster lung cells *in vitro,* but there was no evidence of similar effects in cultured human lymphocytes, or in an *in vivo* assay (micronucleus test in mice). Minoxidil did not cause DNA damage in an alkaline elution assay in Chinese hamster fibroblasts or unscheduled DNA synthesis in rat hepatocytes.

Carcinogenicity

Carcinogenic activity of minoxidil has been investigated following dietary administration to mice at 10-64 mg/kg/day, and following topical administration to mice and rats at 8-80 mg/kg/day. Minoxidil treatment was associated with the development of benign pituitary tumours and malignant mammary tumours in female mice, hepatic adenomas and splenic haemangiosarcomas in male mice, and adrenal medullary and clitoral gland adenomas in female rats. The hepatic tumours were only observed at high dose levels. The development of mammary adenocarcinomas in mice may be related to stimulation of prolactin release.

Tumour development in the pituitary, preputial and clitoral glands may also involve endocrine mechanisms, while the vascular wall tumours in mouse spleen and adrenal medullary tumours in rats may be related to the vasodilator activity of the drug.

In a 12-month photocarcinogenicity study in hairless mice, topical minoxidil did not accelerate the development of dermal tumours initiated by ultraviolet light.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

- MEN'S REGAINE EXTRA STRENGTH
- WOMEN'S REGAINE REGULAR STRENGTH

Excipients: alcohol, propylene glycol and water

- MEN'S REGAINE EXTRA STRENGTH FOAM
- WOMEN'S REGAINE

Excipients: alcohol, water, glycerol, cetyl alcohol, citric acid, lactic acid, stearyl alcohol, polysorbate 60, butyl hydroxytoluene and propellant

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Topical applications

- MEN'S REGAINE EXTRA STRENGTH
- WOMEN'S REGAINE REGULAR STRENGTH

Store below 30°C

Foams

- MEN'S REGAINE EXTRA STRENGTH FOAM
- WOMEN'S REGAINE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

Men's REGAINE Extra Strength topical solution is available in a 60mL and 4x60mL bottle (Aust R 79914).

Women's REGAINE Regular Strength topical solution is available in a 60mL and 3x60mL bottle (Aust R 81852).

Men's REGAINE Extra Strength topical foam is available in a 60g and 2x60g aerosol can (Aust R 277919).

Women's REGAINE topical foam is available in a 60g and 2x60g aerosol can (Aust R 240952).

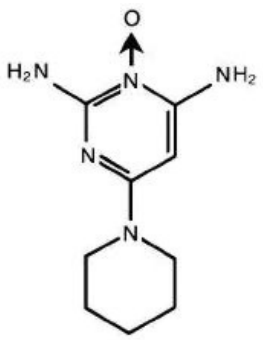
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy

6.7 PHYSICOCHEMICAL PROPERTIES

Minoxidil, a peripheral vasodilator, occurs as a white or off-white, odourless, crystalline solid which is readily soluble in propylene glycol or ethanol, soluble in water to the extent of 2 mg/mL and is almost insoluble in acetone, chloroform or ethylacetate. The chemical name for minoxidil is 2, 4-diamino-6-piperidino-pyrimidine-3- oxide (MW = 209.25).

Chemical structure



CAS No:
38304-91-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia

9 DATE OF FIRST APPROVAL

15th August 2001

10 DATE OF REVISION

30 June 2025

Summary table of changes

Section Changed	Summary of new information
All Sections	Reformatted Product Information to new format.
6.5	Correction of product names Correction of product pack sizes
4.2	Removal of reference to outer cap for solutions
4.4, 4.7 and 4.8	Added safety statement Revised effects on the ability to drive and use machines Update adverse events