SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Minorga 2%, cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Minoxidil 20 mg/ml (2% w/v).

One spray of Minorga 2% cutaneous solution contains 2.8 mg of minoxidil.
Seven sprays are required to apply approximately 1 ml of solution containing 20 mg of minoxidil.

Excipient with known effect: propylene glycol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution.
Clear and colorless or slightly yellow solution with an alcohol odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Minorga 2%, cutaneous solution is indicated for the treatment of alopecia.

Minorga 2%, cutaneous solution is particularly indicated in men who suffer from hair loss or weakening on top of the headand in women with generalized hair weakening.
Minorga 2%, cutaneous solution is indicated in adults aged 18 to 65 years.

4.2 Posology and method of administration

Posology
The dose of 1 ml of Minorga 2%, cutaneous solution should be applied on the scalp twice daily (once in the morning, once at night). This dose should be administered regardless of the affected area size. The total daily dose should not exceed 2 ml.

Paediatric and elderly population
It is not recommended below 18 years old and over 65 years old due to a lack of data on safety and efficacy.

Method of administration
Minorga 2%, cutaneous solution is for external use only. It is not recommended below 18 years and over 65 years due to a lack of data on safety and efficacy.

Minorga 2%, cutaneous solution should be applied in accordance with the instructions and only on the scalp. Minorga 2%, cutaneous solution should be applied only on dry hair and scalp. After applying Minorga 2%, cutaneous solution, hands should be washed thoroughly.

The application of the product may be required twice daily, for four months or more. In all cases, physician should consider discontinuing treatment if no results are observed within 4 months. If hair growth occurs, it is necessary to continue the administration of Minorga 2%, cutaneous solution, twice daily, in order to maintain its effect. After treatment discontinuation with minoxidil topical lotion, hair growth arrest and, sometimes, the return to the previous appearance within the 3 to 4 months after treatment discontinuation have been occasionally reported.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Minorga 2%, cutaneous solution is not indicated in cases of alopecia areata (sudden or unexplained hair loss) or scarring alopecia (characterized by skin with healing characteristics, such as burn or ulcers). Also, Minorga 2%, cutaneous solution should not be used if the hair loss is associated with pregnancy, delivery or severe diseases, such as thyroid malfunction, lupus, loss of sections of hair associated with scalp inflammation, or other diseases.

4.4 Special warnings and precautions for use

Patients with known cardiovascular disease or cardiac arrhythmia should contact a physician before using Minorga 2%, cutaneous solution.

Minorga 2%, cutaneous solution 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.

Minorga 2%, cutaneous solution should only be used on a normal, healthy scalp. Do not use if scalp is red, inflamed, infected, irritated or painful or if using other medications on the scalp.

Some excipients in Minorga 2%, cutaneous solution may cause burning and irritation. 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.

Inhalation of the spray mist should be avoided. Do not swallow.

The patient should stop using Minorga 2%, cutaneous solution and see a doctor if hypotension is detected or if experiencing chest pain, rapid heartbeat, faintness or dizziness, sudden 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 with Minorga 2%, cutaneous solution use.

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.

Paediatric population
Accidental ingestion may cause serious cardiac adverse events. Therefore, Minorga 2%, cutaneous solution has to be kept out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacokinetic drug interaction studies in humans revealed percutaneous minoxidil absorption is enhanced by tretinoin and anthralin, as a result of increased stratum corneum permeability; betamethasone dipropionate increases local tissue concentrations of minoxidil and decreases systemic minoxidil absorption.
Although not clinically proven, there is a theoretical possibility that absorbed minoxidil may potentiate orthostatic hypotension in patients concomitantly taking peripheral vasodilators.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well controlled studies in pregnant women. Animal studies have shown a risk to the fetus at exposure levels that are very high compared to those intended for human exposure. A low, albeit remote, risk of fetal harm is possible in humans (See Section 5.3, Preclinical Safety Data).

Breast-feeding
Systemically absorbed minoxidil is secreted in human milk.

Topical minoxidil should only be used during pregnancy or lactation if the benefit to the mother outweighs the potential risk to the fetus or nursing infant.

4.7 Effects on the ability to drive and use machines

Based on the pharmacodynamic and overall safety profile of minoxidil for topical use, it is not expected that Minorga 2%, cutaneous solution would interfere with the ability to drive or operate machinery.

4.8 Undesirable effects

The frequency of adverse reactions to topical minoxidil solution is defined using 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).
The following adverse events were associated with the use of minoxidil solution (2% and 5% combined) in males and females, at an incidence greater than 1%, and greater than placebo- controlled clinical trials.

Body system	**Incidence**	**Reported adverse event**
Psychiatric disorders	Common	Depression
Nervous system disorders	Very common	Headache
Respiratory, thoracic and mediastinal disorders	Common	Dyspnea
Skin and subcutaneous tissue disorders	Common	Pruritus, hypertrichosis, rash, acneiform rash, dermatitis, inflammatory skin disorder
Musculoskeletal and connective tissue disorder	Common	Musculoskeletal pain
General	Common	Peripheral edema

disorders and administration site conditions		
Miscellaneous	Common	Pain

The following adverse events have been associated with topical minoxidil solution during postmarketing use.

Body system	**Incidence**	**Reported adverse event**
Immune System disorders	Frequency not known	Allergic reactions including angiooedema
Nervous system disorders	Rare	Headache
Cardiovascular disorders	Rare	Palpitations, heart rate increased, chest pain
	Very rare	Hypotension
Skin and subcutaneous tissue disorders	Uncommon	Dry skin, skin exfoliation, rash, temporary hair loss, hypertrichosis, changes in hair texture, changes in hair color
	Rare	Dermatitis contact
General disorders and administration site conditions	Uncommon	Application site pruritus, application site irritation
	Rare	Application site erythema

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 the national reporting system: ADR Reporting - Website: www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

Signs and symptoms
There is no evidence that topically applied minoxidil is absorbed in sufficient quantity to cause systemic effects. When used as directed, overdose is unlikely.
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, there is the potential for a systemic overdose effect.

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

Body system	Incidence	Reported adverse event
Nervous system disorders	Very rare	Dizziness
Cardiovascular disorders	Very rare	Heart rate increased, hypotension
General disorders and administration site conditions	Very rare	Fluid retention resulting in weight increase

Treatment
Treatment of minoxidil overdosage should be symptomatic and supportive. The fluid retention can be managed with appropriate diuretic therapy. Clinical significant tachycardia can be controlled by administration of a beta-adrenergic blocking agent. Symptomatic hypotension should be treated with intravenous administration of saline. Sympathomimetics, such as epinephrine and norepinephrine, should be avoided since these medicinal products cause excessive heart stimulating effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatologicals
ATC Code: D11A X01

Mechanism of action
After topical use, minoxidil demonstrated to stimulate hair growth in patients with androgenic alopecia; however, the mechanism of action of minoxidil is unknown.

Clinical efficacy and safety
The hair loss stabilization is observed in every 4 of 5 patients. Hair growth is subjected to a certain individual variability. However, it may be observed after 4 or more months with regular use of cutaneous solution containing minoxidil. Minoxidil topical application has not shown any systemic effects on the drug absorption when analyzed in controlled studies in normotensive patients or with untreated hypertension.

5.2 Pharmacokinetic properties

Absorption
After topical application, the absorption of minoxidil from normal intact skin is low; in average, only 1.7% (from 0.3 – 4.5%) of the total applied dose is systemically absorbed. In contrast, after oral administration of minoxidil tablets, the drug is mostly absorbed from the GI tract. Once the topical application of minoxidil is discontinued, approximately 95% of systematically absorbed minoxidil is eliminated in the following 4 days. The effects of concomitant skin diseases in the absorption of topically applied minoxidil are unknown.

Biotransformation
The biotransformation of the absorbed minoxidil after topical application was not completely determined. Oral administrated minoxidil is mainly metabolized by the combination with

glucuronic acid in N-oxide position of the pyrimidine ring, but the conversion to more polar metabolites is also observed. The known metabolites have a lower pharmacological effect when compared with minoxidil. 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.

Elimination
Minoxidil and its metabolites are dialyzable; its elimination is mainly urinary.

5.3 Preclinical safety data

Studies in animals have shown risks of adverse effects on fertility and embryo-fetal development only with excessive exposure levels, if compared to those observed in clinical use.

Minoxidil has not shown genotoxic potential. In carcinogenicity studies conducted in rats and mice, the topical administration of minoxidil resulted in increased incidence of hormone-mediated tumors. This tumorigenic/carcinogenic activity is considered to be secondary to hyperprolactinemia, which occurs only with high absorption levels on rodents, and it will not represent a risk to clinical use.

In pre-clinical studies of local tolerance potential primary skin irritations were not observed. Minoxidil has not induced sensitisation by skin contact or IgE-mediated sensitisation and it has not phototoxic or caused photoallergic reactions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Ethanol 96%
Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Flammable product.
Protect from heat. Keep the container tightly closed.

6.5 Nature and contents of container

HDPE Bottle with spray pump / applicators containing 60 ml of solution.

Pack sizes:
1 x 60 ml with 1 removable actuator with nozzle and 1 removable actuator with rod.
3 x 60 ml with 3 removable actuators with nozzle and 2 removable actuators with rod.

Not all pack sizes may be marketed.

6.6 Special precautions for use and other handling

INSTRUCTIONS FOR USE

The instructions for use depend on the type of applicator used.
A. Spray to apply the solution on large areas of the scalp.
B. Spray with applicator to apply the solution on small areas of scalp or in the hair.

A. Spray
It is recommended on large areas of scalp.
1) Take out the cap of the bottle.
2) Place the spray towards the bald area, pressure it once and spread the solution with the tip of the fingers throughout all area. Repeat this procedure six times until complete application of the required dose of 1 mL (i.e. a total of 7 sprays). Avoid inhaling the medicinal product during application.
3) Rinse the spray and replace the cap on the bottle after use to avoid the evaporation of alcohol.

B. Spray with applicator
It is recommended on small areas of scalp or in the hair.
1) Take out the cap of the bottle.
2) Pull the upper part out of the spray, removing it. Adapt the applicator to the spray and make full pressure.
3) Place the spray towards the bald area, pressure it once and spread the solution with the tip of the fingers throughout all area. Repeat this procedure six times until complete application of the required dose of 1 mL (i.e. a total of 7 sprays). Avoid inhaling the medicinal product during application.
4) Rinse the applicator and replace the cap on the bottle after use to avoid the evaporation of alcohol.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

Laboratoires Bailleul S.A.
14-16 Avenue Pasteur
L-2310 Luxembourg – Luxembourg

8. MARKETING AUTHORIZATION NUMBERS

MA1106/00201

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September, 2014
Date of latest renewal: 20th August, 2019

10. DATE OF REVISION OF THE TEXT

07/2025