SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minoxidil 20 mg/ml cutaneous spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients with known effect: 1 ml solution contains 199 mg propylene glycol (E1520) and 494 mg ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution

Clear, colourless to pale yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Minoxidil 20 mg/ml is indicated for the treatment of alopecia androgenetica in women and men aged between 18 and 65.

4.2 Posology and method of administration

Posology

Apply 1 ml Minoxidil 20 mg/ml twice daily (morning and evening) to the affected areas of the scalp.

The daily amount applied, i.e. 2 x 1 ml solution, should not be exceeded, regardless of the size of the affected scalp area.

Paediatric population under 18 years, patients aged 65 years and older

Minoxidil 20 mg/ml must not be used in these patient groups, as no efficacy and safety results from controlled studies are available in these age groups.

Method of administration

Cutaneous use

Prior to applying Minoxidil 20 mg/ml, it must be ensured that the scalp is dry. Minoxidil 20 mg/ml should not be applied to other parts of the body.

Hands should be washed carefully after applying Minoxidil 20 mg/ml, in order to avoid accidental contact with mucous membranes and eyes.

After applying Minoxidil 20 mg/ml, the hair can be styled as normal. However, the scalp should not be moistened for about 4 hours. This will prevent Minoxidil 20 mg/ml from being washed off.

Each pack of Minoxidil 20 mg/ml contains 2 different pump spray applicators:

- pre-assembled applicator for large-area application
- separate applicator with extended tip for smaller areas

Both applicators can be swapped by detaching the one applicator and replacing it with the other.

For a dose of 1 ml 6 spray actuations are needed.

Instructions for use/application

The solution is sprayed directly onto the scalp within the area of hair loss. For this, depress the pump six times. After each actuation, the liquid should be distributed over the affected area with the fingertips, thereby avoiding inhalation of the spray mist.

Duration of use

The onset and extent of hair growth are different in individual patients.

In general, twice-daily treatment for 2 to 4 months is required before an effect is seen. In order to maintain the effect, it is recommended to continue the twice-daily application without interruption. No better result will be achieved by applying Minoxidil 20 mg/ml in larger amounts or more frequently. Regarding a possible therapeutic effect, there is sufficient clinical experience for a treatment period of up to 48 weeks.

If hair re-growth occurs, twice daily applications of Minoxidil 20 mg/ml are necessary for continued hair growth. Anecdotal reports indicate that regrown hair

may disappear three to four months after stopping Minoxidil 20 mg/ml application and the balding process will continue.

If there is no desired therapeutic response within 12 months, treatment should be discontinued.

Too low dosage

If too little Minoxidil 20 mg/ml has been applied or a dose has been missed, the user must not make up for the missing amount. In this case, treatment should be continued at the recommended dose.

4.3 Contraindications

Minoxidil 20 mg/ml must not be used in the following cases:

- in users with a history hypersensitivity to the active substance or to any of the excipients listed in section 6.1,
- if occlusive dressings or other topical medical preparations are being used,
- sudden or uneven hair loss,
- in pregnant women,
- in breast-feeding mothers,
- in users with any scalp abnormality (including psoriasis, sunburn, or if the scalp is damaged by burns or scarring).
- in users with a shaved scalp
- in users with treated or untreated hypertension

4.4 Special warnings and precautions for use

Prior to treatment with Minoxidil 20 mg/ml, the patient should be thoroughly examined and her/his medical history taken.

Endocrinological causes, underlying systemic diseases or malnutrition must be excluded. In these cases, if necessary, a specific treatment should be initiated.

The patient should have a normal, healthy scalp. Minoxidil 20 mg/ml should not be used if the cause of hair loss is not known, in cases of post-partum alopecia, if the scalp is infected or if the scalp is red or painful.

Topical minoxidil is only indicated for the treatment of alopecia androgenetica and should not be used in other types 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.

Minoxidil 20 mg/ml is intended only for external use only on the scalp. Do not apply Minoxidil 20 mg/ml to other parts of the body.

The patient should discontinue the product and consult a doctor if a reduction in blood pressure is detected, or if one or more of the following manifestations occur: chest pain, accelerated heartbeat, asthenia or dizziness, sudden unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp or if other not expected new symptoms appear (see section 4.8).

In some patients, a transient increase in the amount of hair shedding has been observed two to six weeks after the start of treatment. This effect is due to the fact that the resting phase (telogen phase) of the hair cycle is shortened in hair follicles treated with minoxidil and the growth phase (anagen phase) is reached more quickly. This stimulates new hair growth, which pushes the "old", no longer active hairs out of the scalp. This gives the initial impression of increased hair loss. However, it is accompanied by increased hair regrowth. This effect regresses within a few weeks and can be interpreted as a first sign of the minoxidil effect.

If shedding persists (>2 weeks), users should stop using Minoxidil 20 mg/ml and consult their doctor.

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

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.

Treatment with Minoxidil 20 mg/ml should not take place in patients with signs of cardiovascular disease or cardiac arrhythmias or in hypertensive patients, including patients on treatment with antihypertensives.

Isolated cases of slight changes in hair colour and texture have been reported by patients with very fair hair upon concomitant use of other hair care products or after swimming in heavily chlorinated water.

Inadvertent ingestion can cause severe cardiovascular adverse reactions. This product must therefore be kept out of the reach of children.

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

Due to the ethanol and propylene glycol content in Minoxidil 20 mg/ml, repeated spraying of Minoxidil 20 mg/ml on the hair rather than the scalp might result in increased hair dryness and/or stiffness.

Minoxidil 20 mg/ml contains ethanol 96% and can cause eye stinging and irritation. In case of accidental contact with sensitive areas (eyes, skin abrasions, mucous membranes), these must be rinsed with plenty of water.

Inhalation of the spray mist should be avoided.

This medicine contains 199 mg propylene glycol (E1520) in each ml solution.
This medicine contains 494 mg alcohol (ethanol) in each ml solution.
It may cause burning sensation on damaged skin.

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

4.5 Interaction with other medicinal products and other forms of interaction

Minoxidil 20 mg/ml should not be used together with other dermatological products or with agents that enhance skin absorption.

Topical drugs, such as corticosteroids, tretinoin, dithranol or petrolatum, which alter the stratum corneum barrier, could result in increased absorption of minoxidil if applied concurrently. Although it has not been demonstrated clinically, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

Guanethidine has been reported to interact with oral formulations of minoxidil resulting in rapid and pronounced lowering of blood pressure. There is a theoretical possibility that topical minoxidil may also interact with guanethidine.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well controlled studies in pregnant women. Studies in animals 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).

Minoxidil 20 mg/ml must not be used by pregnant women.

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

Minoxidil 20 mg/ml must not be used by breastfeeding mothers.

4.7 Effects on ability to drive and use machines

This product may cause dizziness or hypertension (see section 4.8). If affected,

patients should not drive or operate machinery.

4.8 Undesirable effects

The following frequencies are used for the evaluation of adverse reactions:

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)

The safety of topical minoxidil from clinical trial data is based on data from 7 placebo-controlled randomised clinical trials in adults evaluating either 20 mg/ml or 50 mg/ml minoxidil solution, and two placebo-controlled randomised clinical trials in adults evaluating a 50 mg/ml foam formulation.

Adverse drug reactions (ADRs) identified during clinical trials and postmarketing experience with minoxidil are included in the table below by System Organ Class (SOC).

System Organ Class (SOC)	**Frequency**	**Adverse Drug Reaction (ADR)**
Immune system disorders	Common	Hypersensitivity (including facial oedema, generalised skin rash, general pruritus, facial swelling and throat tightness)
	Not known	Allergic reactions including angioedema (with symptoms such as oedema of the lips, mouth, tongue and throat, swelling of the lips,tongue and oropharynx)
Psychiatric disorders	Not known	Depressed mood
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
Eye disorders	Not known	Eye irritation
Cardiac disorders	Common	Chest Pain
	Uncommon	Palpitations
	Not known	Heart rate increased
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	Pruritus (including rash pruritic generalised and eye pruritus), hypertrichosis (including facial hair growth in women), dermatitis (including contact, allergic, atopic and seborrhoeic dermatitis), dermatitis acneiform, skin rash (including pustular, papular, generalised, vestibular and macular rash) Local side effects on the scalp: stinging, burning, itching, dryness, scaling and folliculitis
	Rare	Changes in hair texture
	Not known	Temporary hair loss, Changes in hair colour Dry skin Skin exfoliation (including exfoliative rash and dermatitis exfoliative) Acne (acneiform rash)
General disorders and administration site conditions	Common	Peripheral oedema
	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, erythema and rash erythematous but can sometimes be more severe and include exfoliation, dermatitis, blistering, bleeding and ulceration)
Investigations	Common	Weight increased

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of intoxication

Application of Minoxidil 20 mg/ml at higher than the recommended dosage and to relatively large body surfaces or areas other than the scalp may possibly lead to increased systemic absorption of minoxidil. To date, there have been no known cases where the topical use of minoxidil solution has resulted in intoxication.

After inadvertent swallowing, the concentration of the active compound minoxidil in Minoxidil 20 mg/ml may lead to systemic effects corresponding to the

pharmacological action of the active substance (2 ml Minoxidil 20 mg/ml contains 40 mg minoxidil, which is equivalent to 40% of the maximum recommended daily dose for the treatment of hypertension).

Signs and symptoms of minoxidil intoxication would probably manifest as an effect on the cardiovascular system in conjunction with salt and fluid retention, as well as tachycardia, hypotension, dizziness and lethargy. If these symptoms occur upon inadvertent ingestion, the patient should seek medical treatment immediately.

Treatment of intoxication
Treatment of minoxidil overdosage should be symptomatic and supportive.
Clinically significant tachycardia can be controlled with β-blockers and oedema with diuretics.
An excessive decrease in blood pressure can be treated by intravenous infusion of physiological saline solution. Sympathomimetics such as adrenaline and noradrenaline are to be avoided due to their excessive cardiotonic effect.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatological preparations; other dermatologicals
ATC code: D11AX01

Minoxidil 20 mg/ml stimulates hair growth in persons with androgenetic alopecia.

Mechanism of action

The exact mechanism of action by which minoxidil stimulates hair growth is not fully known. However, minoxidil can reverse the hair loss process of androgenetic alopecia by:

- increasing the diameter of the hair shaft,
- stimulating hair growth in the anagen phase,
- extending the anagen phase,
- shortening the telogen phase, whereby the anagen phase is reached more quickly.

Pharmacodynamic effects

As a peripheral vasodilator, minoxidil increases the microcirculation to hair follicles. Minoxidil stimulates vascular endothelial growth factor (VEGF) which is probably responsible for the increased capillary permeability and hence shows a high metabolic activity which can be observed during the anagen phase.

Excessive hair loss is halted with regular use after a few weeks. Furthermore, new hair growth may occur. This becomes noticeable at the earliest approximately four months after the start of therapy. A reduction in hair loss can be found in about 80–90% of women.

Cosmetically satisfactory regrowth of terminal hair is observed in up to 40% of patients treated with minoxidil 20 mg/ml after one year of treatment. The success rate rises to approximately 50% with minoxidil 50 mg/ml.

The onset of action and the extent of scalp hair thickening varies depending on the patient. In particular, advanced or more than 10 years' standing androgenetic alopecia is less responsive to minoxidil. This is probably due to the lack of hair roots, the presence of which is necessary for the effect.

Upon discontinuation of treatment, growth of new hair ceases and within 3 to 4 months, the condition reverts to that before the start of therapy

5.2 Pharmacokinetic properties

Absorption

When minoxidil solution is topically applied, about 1 – 2% of the active substance is systemically absorbed, compared to 90-100% with oral formulations. The following study data refer to the topical minoxidil-containing medicinal products of the originator MAH:

In a study on men, the mean minoxidil serum concentration AUC for the 20 mg/ml solution was 7.54 ng*hr/ml, compared to a mean AUC of 35.1 ng*hr/ml for 2.5 mg of an oral formulation. The mean plasma concentration (C_{max}) for the topical solution was 1.25 ng/ml compared to 18.5 ng/ml following oral administration of 2.5 mg.

In another study on men, systemic absorption of a 50 mg/ml foam formulation was about half as much as that of a 50 mg/ml solution. The mean AUC (0- 12 h) and C_{max} for the 50 mg/ml foam, i.e. 8.81 ng*hr/ml and 1.11 ng/ml, respectively, were about 50% of AUC (0-12 h) and C_{max} for the 50 mg/ml solution, i.e. 18.71 ng*hr/ml and 2.13 ng/ml, respectively.

For the 50 mg/ml foam, the time to peak plasma concentration (t_{max}) of 5.42 h was similar to the t_{max} for the solution, i.e. 5.79 h. No haemodynamic effect of minoxidil is evident up to a mean serum concentration of 21.7 ng/ml.

Distribution

The volume of distribution after intravenous administration of 4.6 mg and 18.4 mg minoxidil was 73.1 L and 69.2 L, respectively.

Biotransformation

Following topical administration, about 60% of absorbed minoxidil is metabolised to glucuronides, primarily via the liver.

Elimination

The half-life of topical minoxidil is 22 hours, compared to 1.49 hours with oral dosage forms. 97% of minoxidil is excreted via the urine and 3% via the faeces.
Mean renal clearance of minoxidil and its glucuronides, based on data from oral dosage forms, is 261 ml/min and 290 ml/min, respectively.

Upon discontinuation of treatment, about 95% of the minoxidil absorbed after topical administration is excreted within 4 days.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or carcinogenic potential.

Mutagenicity

Minoxidil showed no evidence of mutagenic or genotoxic potential in a series of *in vivo* and *in vitro* assays.

Carcinogenicity

A high incidence of hormone-induced tumours was observed in rats and mice. These tumours were caused by a secondary hormonal effect (hyperprolactinaemia), which was observed only in rats at extremely high doses and was similar to the effect of reserpine.

The use of topical minoxidil has shown no effect on the hormonal status of women. Therefore, hormone-induced tumours do not pose a carcinogenic risk to humans.

Teratogenicity

Reproductive toxicity studies on rats and rabbits, with very high exposure rates compared to the anticipated exposure level in humans, have revealed signs of maternal toxicity and a risk to the foetus. There is a low risk to the human foetus.

Fertility

Minoxidil doses of more than 9 mg/kg (at least 25 times the human exposure), administered subcutaneously in rats, were associated with a reduced rate of conception and implantation, as well as a reduction in the number of viable pups.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96% (v/v), propylene glycol (E 1520), purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

Shelf life after opening: 6 weeks.

6.4 Special precautions for storage

Do not freeze.
Contains ethanol which is flammable. Store away from heaters or naked flames.

6.5 Nature and contents of container

60 ml white HDPE bottle.

Packs with 60 ml solution or 3 x 60 ml solution.

The medicinal product Minoxidil 20 mg/ml contains two pump spray applicators, one pre-assembled applicator and one applicator with extended tip.

6.6 Special precautions for disposal

The solution is flammable. Do not use while smoking, or near any naked flames or heat source. Avoid exposure of the container and contents to naked flames should be voided during use, storage and disposal.

Any unused medicinal 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(S)

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