SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Minoxidil 2%w/v Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Minoxidil 20 mg/mL (2% w/v)

Contains propylene glycol.

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used topically for the treatment of androgenic alopecia and alopecia areata in women.

4.2 Posology and method of administration

For external use only.

Use only as directed. Do not apply to any area of the body other than the scalp.

A total dose of 1mL should be applied twice per day to the scalp, beginning at the center of the affected area and use fingertips to facilitate drug application for 3-5 minutes. This dose should be used regardless of the size of the affected area. The total daily dose should not exceed 2 mL.

After application wash hands thoroughly.

Apply when the hair and scalp are thoroughly dry.

Pediatric and Elderly Populations

Not recommended. The safety and effectiveness of Minoxidil Spray in children and adolescents below the age of 18 years or adults over 65 years has not been established.

4.3 Contraindications

Hypersensitivity to minoxidil or to any of the ingredients.

4.4 Special warnings and precautions for use

Before starting on Minoxidil Spray the user should determine that the scalp is normal and healthy. This product is not effective for scars or damaged areas on the scalp.

1) Minoxidil Spray is for external use only. Do not apply to areas of the body other

than the scalp.

2) Although extensive use of Minoxidil Spray has not revealed evidence that enough minoxidil is absorbed to have systemic effects, greater absorption because of misuse or individual variability or unusual sensitivity could lead, at least theoretically, to a systemic effect, such as, tachycardia, angina pectoris, or the potentiation of the orthostatic hypotension produced by guanethidine, and patients need to be aware of this.

3) Patients with known cardiovascular disease or cardiac arrhythmia should contact a physician before using this product. Minoxidil Spray is recommended for use only in healthy adults with normal cardiovascular status.

4) Patients with a history of underlying heart disease should be aware that adverse effects in them might be especially serious.

5) The patient should stop using this product and see a doctor, if systemic effects or serious skin disease reactions are detected.

6) This product contains ethanol which may cause burning and irritation of the eye. 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.

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

8) The efficacy of using Minoxidil Spray with skin diseases or those who also use topical corticosteroids or other skin products is not yet clear.

9) The patient should stop using this product and see a doctor if hypotension is detected 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 or other unexpected new symptoms occur.

4.5 Interaction with other medicinal products and other forms of interaction

There are currently no known drug interactions associated with the use of Minoxidil Spray. Although it has not been clinically demonstrated, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension in patients currently taking peripheral vasodilators.

4.6 Fertility, pregnancy and lactation

The effects of Minoxidil Spray in pregnancy are unknown.

Minoxidil Spray should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Most frequently reported adverse reactions in clinical trials with Minoxidil Spray are

minor dermatological reactions. Local irritation is the most common adverse reaction reported, including scaling, erythema/flushing, dermatitis, dry skin, hypertrichosis (In areas other than where Minoxidil Spray was applied), burning sensation and rash. Infrequently reported adverse reactions included allergic reactions (sensitivity, hives, generalized erythema and facial swelling); dizziness; tingling sensation; headache; weakness; neuritis; edema; eye irritation; altered taste; ear infection (particularly otitis externa) and visual disturbances. Rarely reported adverse reactions included alopecia, hair abnormalities, chest pain, blood pressure changes, pulse changes, hepatitis and kidney calculi.

4.9 Overdose

Accidental ingestion has the potential of producing systemic effects related to the action of the drug. Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects associated with sodium and water retention. Tachycardia, hypotension, dizziness and lethargy can also occur.

If encountered, the consumer should see a physician.

Fluid retention can be managed with appropriate diuretic therapy. Clinically significant 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by the following means:

- increasing the diameter of the hair shaft

- stimulating anagen growth

- prolonging the anagen phase

- stimulating anagen recovery from the telegon phase

As a peripheral vasodilator minoxidil enhances microcirculation to hair follicles. The Vascular Endothelial Growth Factor (VEGF) is stimulated by minoxidil and VEGF is presumably responsible for the increased capillary fenestration, indicative of a high metabolic activity, observed during the anagen phase.

5.2 Pharmacokinetic properties

There is some evidence from in vitro studies that minoxidil reversibly binds to human plasma proteins. However, since only 1-2% of topically applied minoxidil is absorbed, the extent of plasma protein binding occurring in vivo after topical application would be clinically insignificant. The volume of distribution of minoxidil after intravenous

administration has been estimated at 70 litres.

Approximately 60% minoxidil absorbed after topical application is metabolised to minoxidil glucuronide, primarily in the liver. 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.

Cardiac effects of minoxidil in dogs are species-specific in terms of the low doses that cause profound haemodynamic effects and associated changes in the heart. Available data indicate that similar cardiac effects do not occur in humans treated topically or orally with minoxidil.

Mutagenicity

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

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 exposure. A low, albeit remote, risk of foetal harm is possible in humans.

Fertility

Preclinical fertility studies in rats have shown minoxidil doses equal to or greater than 3 mg/kg/day (at least 8-fold human exposure) when administered orally and greater than 9 mg/kg/day (at least 25-fold human exposure) when administered subcutaneously were associated with reduced conception and implantation rates as well as a reduction in the number of live pups.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol

Ethanol

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Well closed, store at controlled room temperature (10°C-30°C).

6.5 Nature and contents of container

Minoxidil Spray, 2% × 60 mL, is kept in a plastic bottle with a metering dose manual pump. Packs contain one bottle.

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 avoided during use, storage and disposal. Any unused product or waste material should be disposed of in accordance with the local requirements.

7.MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Jewim Pharmaceutical (Shandong) Co., Ltd.

Taian Hi-Tech Industrial Development Zone, Shandong, China

Post Code: 271000

Tel: +86-538-8926688

Fax: +86-538-8926066

ERNEST CHEMISTS LIMITED - Adjacent Provident Towers, Ring Central, kwame Nkrumah Circle Accra, P.O. BOX 3345, Ghana

8.MARKETING AUTHORISATION NUMBER

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11/2025