National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Minoxidil spray 2% or 5% - 60ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One bottle of 60ml solution contains 2% or 5% minoxidil.
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

It is spray.

4. Clinical particulars

4.1 Therapeutic indications

ALOREPAIR® is a topical solution for the treatment of alopecia androgenetica (male pattern baldness of the vertex of the scalp and in females as diffuse hair loss or thinning of the frontoparietal areas). It promotes hair growth and the epithelium of hair bursa. The response is better when the patients use ALOREPAIR® directly after hair loss. At least four months of twice daily applications are generally required before evidence of hair growth can be expected. If patient respond to treatment, he will need to continue using ALOREPAIR® to maintain hair growth.In the treatment of alopecia androgenetica (male-pattern baldness) 1mL of a 2% or 5% solution of ALOREPAIR® is applied twice daily to the scalp. The 5% solution is not recommended for women.

4.2 Posology and method of administration

Hair and scalp should be thoroughly dry prior to topical application of Regaine for Men Extra Strength. A dose of 1 ml Regaine for Men Extra Strength cutaneous solution should be applied to the total affected areas of the scalp twice daily. The total dosage should not exceed 2 ml. If fingertips are used to facilitate drug application, hands should be washed afterwards.
It may take twice daily applications for 2 months or more before evidence of hair growth can be expected. If hair re-growth occurs, twice daily applications of Regaine for Men Extra Strength are necessary for continued hair growth. Anecdotal reports indicate that re-grown hair may disappear three to four months after stopping Regaine for Men Extra Strength application and the balding process will continue.
Users should discontinue treatment if there is no improvement after one year.
Special populations
There are no specific recommendations for use in patients with renal or hepatic impairment.
Pediatric and Elderly Populations
Not recommended. The safety and effectiveness of Regaine for Men Extra Strength in children and adolescents below the age of 18 years or adults over the age of 65 years has not been established.
Method of Administration
For topical use only.
The method of application varies according to the disposable applicator used:
Pump spray applicator: this is useful for large areas. Aim the pump at the centre of the bald area, press once and spread with fingertips over the entire bald area. Repeat for a total of 6 times to apply a dose of 1 ml. Avoid breathing spray mist.
Extended spray-tip applicator: this is useful for small areas, or under hair. The pump spray applicator must be in place in order to use this additional applicator. Use in the same way as the pump spray.

4.3 Contraindications

ALOREPAIR® is contraindicated in patients with Arterial hypertension, who are hypersensitivity to minoxidil, propylene glycol or ethanol and any other component of the preparation, pregnant and lactating.

4.4 Special warnings and precautions for use

Local abrasion or dermatitis of the scalp may increase absorption and hence increase the risk of side effects; patients with history of or existing heart disease should be advised of potential serious adverse effects; observing patients for tachycardia and fluid retention; patients should be monitored for increased heart rate and weight gain or other systemic effects (discontinue use if systemic effects occur); avoid use

in pregnancy, lactation and children below 18 years of age; avoid contact with eyes and any irritated skin (wash with large amount of water if ALOREPAIR® gets into the eyes, mucous membranes or sensitive skin areas).
Do not apply on other parts of the body and stop use when changes in hair colour and texture is noticed.

4.5 Interaction with other medicinal products and other forms of interaction
Avoid co-administration with other topical agents including topical corticosteroids, retinoids, and petrolatum or agents that are known to enhance cutaneous drug absorption. Avoid administration with guanethidine. Ask a doctor before use if you have a heart disease.

4.6 Pregnancy and Lactation
It is contraindicated in pregnant and lactating.
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).
Lactation
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
This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects
Most commonly, itching and other skin irritations of the treated area of the scalp.
Infrequent adverse reactions including allergic reactions (sensitivity, hives, generalized erythema and facial swelling); dizziness; tingling sensation; headache; weakness; neuritis; oedema; eye irritation; altered taste; ear infection (otitis externa); and visual disturbances have been reported. Rarely reported adverse reactions included alopecia, hair abnormalities, chest pain, blood pressure changes, pulse changes, hepatitis, and kidney stones.

4.9 Overdose
The symptoms include Itching and skin irritation. Washing the area with large amount of water and reducing the dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties
When applied topically, ALOREPAIR® topical solution has been shown to stimulate hair growth in individuals with alopecia androgenetica (male pattern baldness). Although the exact mechanism of action of ALOREPAIR® in the treatment of alopecia androgenetica is not known, there may be more than one mechanism by which minoxidil stimulates hair growth; they include: vasodilation of the microcirculation around the hair follicles which may stimulate hair growth; direct stimulation of the hair follicle cells to enter into a proliferative phase: resting phase (telogen) follicles being stimulated to pass into active phase (anagen) follicles; alteration of the effect of androgens on genetically predetermined hair follicles: minoxidil may affect the androgen metabolism in the scalp by inhibiting the capacity of androgens to affect the hair follicles.

5.2 Pharmacokinetic properties
Minoxidil is a potent oral vasodilator acting on the arteriolar side of the circulation. Reflex tachycardia and sodium retention are consequences of increased sympathetic activity. Its biotransformation is 90% hepatic, with no evidence of accumulation of minoxidil when it is given chronically in patients with either normal renal function. The half-life is approximately 3 hr, regardless of whether the dose is given singly or on a multiple-dose basis. It is widely distributed throughout the body, and hence its volume of distribution is greater than 200 liters. There appears to be a dissociation between the peak plasma concentration and the antihypertensive response owing to the fact that minoxidil rapidly leaves the plasma on its way to the principal site of action, that is, the vascular smooth-muscle receptor site. No

tolerance or refractoriness appears to develop with long-term minoxidil administration.

5.3 Preclinical safety data

Minoxidil, a long-acting peripheral vasodilator, was given to mice, rats, rabbits, miniature pigs, rhesus monkeys, and dogs for toxicologic evaluation The drug has a low order of acute ip and po toxicity. Teratological studies in pregnant rats and rabbits have negative results. Single daily oral doses of 20 mg/kg for 1 month were nontoxic to pigs and monkeys. Dose levels of 7 mg/kg in monkeys and 30 mg/kg in rats for 1 year did not indicate toxicity. Single daily doses of 1 to 20 mg/kg for 1 month produced a specific right atrial lesion in dogs only. The lesion was found in some but not in all dogs given a single oral dose of 3, 10, or 30 mg/kg 6 days per week for 1 year. There is some evidence that the basis for the lesion in dogs is physiologic rather than toxicologic. Because of a need for combination drug therapy in those clinical cases where a long-acting peripheral vasodilator would be useful, studies of minoxidil in combination with diuretic, β-adrenergic-blocking, and immunosuppressive agents were carried out. Findings similar to those produced by minoxidil alone were seen with these combinations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%), Propylene glycol and Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Flammable: keep away from fire or flame.
Storage: Store below 30°C.

6.5 Nature and contents of container

Primary components: Plastic bottle and metering dose manual pump.
Volume of bottle is 60ml.
Plastic bottle and metering dose manual pump comply with in-house standard.

6.6 Special precautions for disposal

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

7. APPLICANT/MANUFACTURER

Name: JEWIM PHARMACEUTICAL (SHANDONG) CO., LTD
Address: Tai'an High-tech Industrial Development Zone, Shandong Province, China
Tel: 0538-8926688
Fax: 0538-8926066
Email: jwzy@jewim.com.cn