## Core Safety Profile

<table>
<thead>
<tr>
<th>Active substance:</th>
<th>Minoxidil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical form(s)/strength:</td>
<td>Cutaneous solution, 2% w/w, 5% w/w</td>
</tr>
<tr>
<td>P-RMS:</td>
<td>IE/H/PSUR/0003/002</td>
</tr>
<tr>
<td>Date of FAR:</td>
<td>01.09.2011</td>
</tr>
</tbody>
</table>
4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients.

4.4 Special Warnings and Special Precautions for Use

Patients with known cardiovascular disease or cardiac arrhythmias should contact a physician before using minoxidil.

Minoxidil 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.

Minoxidil 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 the product 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.

The consumer should stop using the product and see a doctor 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.

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

4.5 Interactions

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.

4.6 Pregnancy and Lactation

Systemically absorbed minoxidil is secreted in human milk.

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).

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 Ability to Drive and use Machines
Unlikely to produce an effect.

4.8 Undesirable Effects

Clinical Trials – Minoxidil Solution

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 in seven placebo-controlled clinical trials.

Very Common: ≥ 10 % (≥ 1/10)
Neurological: headache

Common: ≥ 1 % and < 10 % (≥ 1/100 and < 1/10)
Respiratory: dyspnea
Dermatological: pruritus, hypertrichosis, rash, acneform, dermatitis, inflammatory skin disorder
Musculoskeletal: musculoskeletal pain
Metabolic/Nutritional: peripheral edema
Psychiatric: depression
Miscellaneous: pain

Clinical Trial – Minoxidil Foam

The following adverse events were associated with the use of 5% minoxidil foam in males, at an incidence greater than 1 %, and greater than placebo in one placebo-controlled clinical trial.

Common: ≥ 1 % and < 10 % (≥ 1/100 and < 1/10)
Body as a Whole: headache
Skin: pruritus, rash
Cardiovascular: hypertension

Post Marketing Experience - Minoxidil Solution

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

Uncommon: ≥ 0.1% and < 1% (≥ 1/1000 and < 1/100)
General Disorders and Administration Site Conditions: application site pruritus, application site irritation.
Skin and Subcutaneous Tissue Disorders: dry skin, skin exfoliation, rash, temporary hair loss, hypertrichosis, changes in hair texture, changes in hair color.

Rare: ≥ 0.01% and < 0.1% (≥ 1/10,000 and < 1/1000)
General Disorders and Administration Site Conditions: application site erythema
Skin and Subcutaneous Tissue Disorders: dermatitis contact.
Nervous System Disorders: headache.
Cardiovascular Disorders: Palpitations, Heart Rate Increased, Chest Pain

**Very Rare:** < 0.01% (< 1/10,000)
Cardiovascular Disorders: hypotension.

### 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:

**Very Rare:** < 0.01% (< 1/10,000)
Cardiovascular Disorders: heart rate increased, hypotension
General Disorders: fluid retention resulting in weight increase
Nervous System Disorders: dizziness

**Treatment**

Treatment of minoxidil overdosage should be symptomatic and supportive.