Core Safety Profile

Active substance: 17-Alpha-Oestradiol
Pharmaceutical form(s)/strength: Cutaneous solution
P-RMS: DE/H/PSUR/0034/001
Date of FAR: 31.01.2012
4.3 Contraindications

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

4.4 Special warnings and precautions for use

There has been no experience in people under 18 years of age. During use, the scalp may become oilier and drier. 

*Contact of the product with the eyes should be avoided*

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There is no specific experience of the use of /.../ in pregnancy and lactation. /.../ should not be used during pregnancy or during lactation unless clearly necessary.

4.7 Effects on ability to drive and use machines

No studies of the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The most commonly reported adverse effect is skin discomfort occurring in approximately 7% of patients.

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Frequency</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin and Subcutaneous disorders</td>
<td>Common</td>
<td>Skin discomfort</td>
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Adverse reactions reported by more than two patients in the clinical studies are included.

During post marketing surveillance, skin burning sensation, redness and pruritus have been observed.

4.9 Overdose

There have been no reports of intoxication in humans to date. The active substance is toxicologically irrelevant in the concentration present. In the event of accidental oral ingestion, the principal symptoms would be those of 2-propanol intoxication.