

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stiefel Anti-Perspirant 20 % w/w Cutaneous Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Aluminium Chloride Hexahydrate 20.00 % w/w

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

A clear, colourless to very pale green liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of hyperhidrosis of the armpits (axillae), the hands and the feet.

4.2 Posology and method of administration

For topical application only.

Apply to affected areas at night, remove by washing in the morning. Use once each night until sweating stops. Use may be reduced to twice weekly and then once weekly or even less frequently.

4.3 Contraindications

Stiefel Anti-Perspirant Solution should not be used in the armpits within 12 hours of the use of depilatories or shaving.

Stiefel Anti-Perspirant Solution should not be used immediately after bathing.

4.4 Special warnings and precautions for use

Application should be restricted to the affected area only.

The affected areas to be treated should be perfectly dry.

The product should not be applied to broken or irritated areas of skin. Care should be taken to avoid contact with the eyes or mucous membranes.

Bathing should be avoided immediately before application of the product. At least one hour should be allowed following bathing.

Armpits should not be shaved for 12 hours before or after use of the product.

The reduction in sweating produced by Stiefel Anti-Perspirant Solution may result in temporary irritation or redness. If this becomes excessive, treatment should be stopped temporarily.

The substance should not be allowed to contact clothing.
For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There are no restrictions on the use of Stiefel Anti-Perspirant Solution during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Excessive topical use may cause irritation, erythema and scaling. If affected apply emollients or hydrocortisone cream 1% as necessary.

4.9 Overdose

Ingestion can cause nausea, vomiting, diarrhoea and burning in the mouth and throat. Administer copious quantities of water and antacids as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The efficacy of aluminium chloride in the treatment of hyperhidrosis has been demonstrated during more than 60 years' clinical use. Its anti perspirant action has been shown to be due to a mechanical blockage of the upper portion of the eccrine sweat duct, leading to asymptomatic retention of sweat.

5.2 Pharmacokinetic properties

Aluminium chloride has been detected in the stratum corneum and lower layers of the epidermis following topical application but has not been found in the dermis. Systemic absorption is not anticipated.

5.3 Preclinical safety data

Not applicable. Aluminium chloride has been in wide-spread use for many years. The relevant information is given in section 4 of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C. Replace cap tightly after use. Store upright. Avoid flame.

6.5 Nature and contents of container

High density polyethylene bottle incorporating a natural polystyrene roll-on ball and cap containing 60ml. The bottles are presented in a carton together with an explanatory leaflet.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA144/41/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st January 1990

Date of last renewal: 31st January 2005

10 DATE OF REVISION OF THE TEXT

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