Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anhydrol Forte 20% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Aluminium Chloride Hexahydrate 20.0 % w/v.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
Clear, colourless, evaporative solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of hyperhidrosis specifically involving axillae, hands or feet.

4.2 Posology and method of administration

For adults, children and the elderly.

Apply to the affected sites at night, as required, and allow to dry. Wash off in the morning.

4.3 Contraindications

Not to be used in cases of sensitivity to any of the ingredients.

Not to be used in axillae within 12 hours of using depilatories or shaving.

Not to be used immediately after bathing.

4.4 Special warnings and precautions for use

Care should be taken to restrict the application to the affected sites only.
Keep away from the eyes and mucous membranes.
Care should be taken to avoid Anhydrol Forte coming into direct contact with clothing, polished surfaces, jewellery or metal.
Replace cap tightly after use.
For external use only.

4.5 Interaction with other medicinal products and other forms of interactions

Do not bathe immediately before use and, if the axillae are treated, do not shave or use depilatories on this area within 12 hours before or after use.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

If applied too frequently, Anhydrol Forte may cause irritation which should be treated with a mild topical hydrocortisone cream.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

See section 4.8 above (undesirable effects).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aluminium chloride is believed to denature the protein content of sweat issuing from eccrine glands, and to combine with the intraductal keratin fibrils, producing a functional closure. The antibacterial action of the aluminium ion also precludes the development of miliaria. Accordingly, there is no secondary inflammation. The intraluminal pressure rises to the point where it acts as a feedback system, shutting off acinar secretion.
The formulation of Anhydrol Forte has been tested in widespread clinical practice, and has been shown to be effective when used in accordance with the recommended instructions.

5.2 Pharmacokinetic properties

As the active ingredient is applied in an alcoholic solution of low surface tension, it therefore penetrates into the terminal pores of the sweat ducts, when applied, as recommended, to dry skin. The alcohol then evaporates off, leaving the salt deposited in close contact with the lining of the duct. The use of the preparation is restricted to small areas of skin, namely the axillae, hands or feet, to ensure that there are no detrimental effects from widespread obstruction of sweating.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial Methylated Spirit

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Highly flammable.
Store upright and away from flames.

6.5 Nature and contents of container

HDPE bottles (nominal 10 or 60 ml capacity) with polypropylene roll on applicators and polystyrene or polypropylene screwcaps, containing 10 or 60 ml of solution.
Type I glass bottles (nominal 10 or 60ml capacity) with polypropylene roll on applicators and urea formaldehyde screwcaps, containing 10 or 60ml of solution.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th March 1982

Date of last renewal: 16th December 2006.

10 DATE OF REVISION OF THE TEXT

December 2020