

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Anhydrol Forte

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Aluminium chloride hexahydrate 20.0% w/v.

### **3 PHARMACEUTICAL FORM**

Cutaneous Solution,  
Clear, colourless, evaporative cutaneous 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. Contra-Indications**

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

#### **4.4. Special Warnings and Special Precautions for Use**

Care should be taken to restrict the application to the affected sites only.

Keep away from the eyes.

Care should be taken to avoid Anhydrol Forte coming into direct contact with clothing, polished surfaces, jewellery or metal.

Replace cap tightly after use.

#### **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 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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

#### **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. Pre-clinical Safety data**

None stated.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of Excipients**

Industrial methylated spirit 95%

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf-Life**

The expiry date is indicated on the printing materials.

### **6.4. Special Precautions for Storage**

Highly flammable. Store at room temperature, not exceeding 25<sup>0</sup>C. Store upright and away from flames.

### **6.5. Nature and Contents of Container**

60 ml HDPE bottle with roll on applicator and screwcap.

### **6.6 Instructions for Use/Handling**

Not applicable.

## **7. MARKETING AUTHORIZATION HOLDER**

Trupharm Marketing 1985, P.O.B. 8105, Nethanya, Israel.

## **8. MARKETING AUTHORIZATION NUMBER**

603827252

## **9. MANUFACTURER**

Dermal Laboratories LTD, Tatmore Place, Gosmore, Hitchin, Herts, UK.

Revised in November 2022 according to MOH guidelines.

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