Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Driclor Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Aldioxa 0.20 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous powder
An off-white, absorbent, light free flowing cutaneous powder with a slight odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Driclor Powder is indicated in the management of intertrigo, hyperhidrosis and bromidrosis and in the prevention of Tinea pedis and related conditions.

4.2 Posology and method of administration

The affected area should be dried as thoroughly as possible before applying Driclor Powder. Driclor Powder should be smoothed over the surface of the skin, between joints and folds.

4.3 Contraindications

Known hypersensitivity to the ingredients.

4.4 Special warnings and precautions for use

As with all powders, care should be taken to avoid inhalation.

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 Driclor Powder in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Driclor Powder contains aluminium dihydroxyallantoinate. Aluminium exerts a bacteriostatic action while allantoin promotes phagocytosis.

Allantoin also acts as a hydrogen bond breaker, reducing hyperkeratinisation by its action on the intercellular cement. The leucocytic stimulant effects of allantoin cause debridement of necrotic tissue and generation of new tissue.

The anti-irritant action of aluminium dihydroxyallantoinate may be dependent on the neutralisation and/or detoxication of irritants. This together with its healing and tissue normalising actions may be responsible for its antipruritic effects. The antibacterial action prevents the formation of bacterial metabolites or toxins which cause odours.

Microporous cellulose is a non-caking water absorbant powder which exerts a drying action by absorbing fluid from the skin surface by capillary action.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chloroxylenol
Microcrystalline Cellulose
Talc
Perfume 6A

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Keep the container tightly closed.

6.5 Nature and contents of container

Sifter-top plastic containers of 50 g.

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

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8 MARKETING AUTHORISATION NUMBER

PA 144/12/2

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Date of last renewal: 01 October 2004

10 DATE OF REVISION OF THE TEXT

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