

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Epaderm Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Emulsifying Wax BP	30 % w/w
Yellow Soft Paraffin BP	30 % w/w

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A pale yellow translucent emulsifying ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For general use as an emollient to moisturise and soften dry skin. Epaderm may be used instead of soap.

4.2 Posology and method of administration

Topical.

Adults, the elderly and children:

Epaderm should be massaged into the skin as often as required. Epaderm may also be added to the bath by first producing a dispersion with hot water. When used as a bath additive care should be taken as it will make the surface slippery.

4.3 Contraindications

There are no specific contraindications to the use of Epaderm apart from known sensitivity to any of the components.

4.4 Special warnings and precautions for use

If the condition does not improve or is aggravated, discontinue use and consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

The effect of Epaderm during pregnancy and lactation has not been studied. Therefore, there are no recommendations in these conditions.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Overdose is highly unlikely. If necessary, medication should be removed by washing with warm water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Epaderm is an emollient preparation for topical application to the skin.

5.2 Pharmacokinetic properties

Not applicable as this is a topical preparation.

5.3 Preclinical safety data

The active ingredients are well documented therapeutic agents and therefore preclinical or toxicological data are available from the public domain and not submitted in this instance. Emulsifying wax and yellow soft paraffin are both subjects of pharmacopoeias monographs both being quoted in the BP.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin Ph. Eur.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C in a dry place.

Keep the tub/pot tightly closed.

6.5 Nature and contents of container

500g: White polypropylene securitub with tamper evident closure.

125g: White polypropylene securipot with tamper evident closure.

50g: White polypropylene securipot with tamper evident closure.

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

Medlock Medical Limited
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8 MARKETING AUTHORISATION NUMBER

PA 1175/4/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 6 March 2003

10 DATE OF REVISION OF THE TEXT

February 2005