

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Cetraben Emollient Cream

2. Qualitative and Quantitative Composition

White Soft Paraffin 13.2% w/w
Light Liquid Paraffin 10.5% w/w

For excipients see section 6.1.

3. Pharmaceutical Form

Cream.

A thick white cream with the characteristic odour of paraffin oil.

4. Clinical Particulars

4.1. Therapeutic indications

Cetraben Emollient Cream is an emollient, moisturising and protective cream for the symptomatic relief of red, inflamed, damaged, dry or chapped skin, especially when associated with endogenous or exogenous eczema.

4.2. Posology and method of administration

Cetraben Cream should be applied to the dry skin areas as often as required and rubbed in.

4.3. Contraindications

Hypersensitivity to any of the ingredients.

4.4. Special warnings and precautions for use

None known.

4.5. Interactions with other medical products and other forms of interaction

None known.

4.6. Pregnancy and lactation

No special precautions are required.

4.7. Effects on ability to drive and use machines

None.

4.8. Undesirable effects

Very rarely, mild allergic skin reactions including rash and erythema have been observed, in which case use of the product should be discontinued.

4.9. Overdose

None reported.

5. Pharmacological Properties

5.1. Pharmacodynamic properties

ATC Code: D02A X (Other Emollients and Protectives)

The ingredients of Cetraben Cream have an emollient, moisturising and protective properties.

5.2. Pharmacokinetic properties

Cetraben cream acts only on the skin.

5.3. Preclinical safety data

Not applicable.

6. Pharmaceutical Particulars

6.1. List of excipients

Emulsifying wax
Cetyl stearyl Alcohol
Glycerin
Butylparaben
Methylparaben
Ethylparaben
Propylparaben
Phenoxetol
Citric Acid
Purified water

6.2. Incompatibilities

None known.

6.3. Shelf life

Three years

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

Polypropylene jars with a pump dispenser of 1050g, 500g, 150g and 50g, polyethylene screw capped jars* or tubes of 125g, polyethylene tubes of 50g and polyethylene tubes of 20g.

* not currently marketed.

6.6. Special precautions for disposal

Not applicable.

7. Marketing Authorisation Holder

Pharma Health Care Ltd
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8. Marketing Authorisation Number

PL 17320/0001

9. Date of First Authorisation/Renewal of the Authorisation

21/09/2006

10. Date of Revision of the Text

25/09/07