

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

Excipient(s) with known effect

Butylparaben 0.022% w/w

Ethylparaben 0.014% w/w

Methylparaben 0.057% w/w

Emulsifying wax 5.2% w/w

(Containing Sodium laurilsulfate 0.49% w/w and Cetostearyl alcohol)

Cetostearyl alcohol 6.21% w/w

For the full list of 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

This medicine contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 0.49% w/w Sodium laurilsulfate per application which may cause local skin reactions (such as stinging or burning sensations or increase skin reactions caused by other products when applied on the same area.

This medicine contains parahydroxybenzoates which may cause allergic reactions (possibly delayed)

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, 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.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

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 (Containing Cetostearyl alcohol and Sodium laurilsulfate)
Cetostearyl Alcohol
Glycerin (E422)
Butylparaben
Methylparaben (E218)
Ethylparaben (E214)
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 screw capped jars or tubes of 50g

* not currently marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Genus Pharmaceuticals

Linthwaite,

Huddersfield,

HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 06831/0259

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

21/09/2006

10 DATE OF REVISION OF THE TEXT

04/10/2019