

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Eucerin Intensive 10% w/w Urea Treatment Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea 10% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White, shiny cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of ichthyosis, xeroderma, hyperkeratosis and other chronic dry skin conditions such as atopic eczema (dermatitis).

4.2 Posology and method of administration

Eucerin Intensive 10% w/w Urea Treatment Cream should be applied sparingly twice daily to the affected areas of skin and rubbed in. It should not be allowed to come into contact with the eyes or mucosae. It should not be applied on large areas in patients with renal insufficiency.
The duration of use depends on the particular condition of the skin and should be established on an individual basis.

4.3 Contraindications

Eucerin Intensive 10% w/w Urea Treatment Cream should not be used in patients with a known hypersensitivity to any of the ingredients. It should not be used to treat excoriated acute inflammation of the skin. It should not be used on large areas in patients with renal insufficiency.

4.4 Special warnings and precautions for use

A doctor should be consulted if symptoms persist.

4.5 Interaction with other medicinal products and other forms of interactions

Urea may potentiate the release of active substances from topical preparations and their penetration into the skin. This is known in particular for corticosteroids, dithranol and fluorouracil.

4.6 Fertility, pregnancy and lactation

There are no known risks.

4.7 Effects on ability to drive and use machines

No effects would be anticipated.

4.8 Undesirable effects

Local skin irritation may sometimes occur particularly if the product is applied in acute inflammatory skin conditions or to sensitive skin. If the condition is aggravated or if there is no improvement the doctor should be consulted.

4.9 Overdose

Excessive topical use or overdose may cause skin irritation. This tends to resolve quickly and automatically when use of the product is discontinued.

Accidental ingestion of the cream is unlikely to produce toxic effects as oral doses of up to 100g/day urea (present in more than six 150g tubes of cream) are considered safe.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D02AE Carbamide products

Urea acts as a hydrating and keratolytic agent.

5.2 Pharmacokinetic properties

Only a small percentage of the amount of the urea applied to the skin penetrates to the epidermis and dermis. Urea is primarily excreted unchanged in the urine. A small amount is also eliminated in the sweat.

5.3 Preclinical safety data

In man, doses of up to 80g/day iv or 100g/day p.o. urea are considered safe. Such high doses of urea are not absorbed following topical use, even when the whole body is treated exclusively externally.

Very limited preclinical data are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Light Liquid Paraffin
Sodium Lactate Solution
Magnesium Stearate
Microcrystalline Wax
Triglycerol Diisostearate
Isopropyl Palmitate
Wool Alcohols
Magnesium Sulphate
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Internally coated aluminium tube with a plastic screw cap.

Pack sizes: 15 ml, 50 ml, 100 ml and 150 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Beiersdorf AG
Unnastrasse 48
20245 Hamburg
Germany

8 MARKETING AUTHORISATION NUMBER

PA1106/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 September 2004

Date of last renewal: 09 February 2008

10 DATE OF REVISION OF THE TEXT

April 2019 CRN008V04