

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Curemid 50 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains carbamide (urea) 50 mg.

Excipients with known effect:

Ethyl parahydroxybenzoate, methyl parahydroxybenzoate, cetostearyl alcohol, propylene glycol.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream.

White cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Moisturizing treatment of dry skin of different origin.

4.2 Posology and method of administration

Posology

The cream is applied when needed, preferably several times a day and always after contact with water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Avoid applying cream into eyes, nose, ears, open wounds or mucous membranes. Curemid cream contains ethyl and methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed). Curemid cream contains cetostearyl alcohol which may cause local skin reactions (eg contact dermatitis). Curemid cream contains propylene glycol.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Curemid can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

There is no evidence that Curemid affects the ability to drive or use machines.

4.8 Undesirable effects

The cream can cause transient, local sensation of burning and a feeling of heat. The face is particularly sensitive.

Common (1>100)

Skin and subcutaneous tissue disorders: Transient sensation of burning, feeling of heat.

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 national reporting system** listed in [Appendix V](#).*

4.9 Overdose

Not relevant as the medicinal product is for external use only.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Protectives and emollients.

ATC code: D02AE01

Mechanism of action

Curemid cream contains 5% urea in an emollient cream base. The water binding properties of urea contributes to normalization of dry skin.

Clinical efficacy

The effect of Curemid in recurrent atopic eczema was investigated in a small clinical study. Patients with atopic eczema treated defined atopic lesions with a strong steroid cream (betamethasone valerate 0.1% cream) for 3 weeks. Thereafter, eczema free patients were randomized to either maintenance treatment with Curemid or no treatment. The time to recurrence of eczema was measured for 26 weeks. The study showed that Curemid significantly prolonged the time to eczema recurrence (p0.01) compared with no treatment. Of the patients who received maintenance treatment, 68% of patients treated with Curemid were eczema-free after 26 weeks (median time to recurrence was 180 days). In the untreated group, 32% were eczema-free during the corresponding period (median time to recurrence 30 days). The absolute risk reduction was 36% and the relative risk reduction was 53%.

5.2 Pharmacokinetic properties

Absorption

The systemic absorption of urea has not been studied but is considered to be negligible.

5.3 Preclinical safety data

Preclinical data is not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium chain triglycerides
Polysorbate 60
Cetostearyl alcohol
Hydrogenated canola oil
Propylene glycol
Carbomer
Dimethicone
Hard paraffin
Glycerol polymethacrylate
Ethyl parahydroxybenzoate (E 214)
Methyl parahydroxybenzoate (E 218)
Sodium lactate solution
Lactic acid
Glyceryl stearate
Polyoxyethylene stearate
Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Plastic tube (polyethylene), 100 g, with snap cap.
Plastic tube (polyethylene), 210 g, with snap cap.
Plastic jar (polypropylene) with pump, 500 g.
Plastic jar (polypropylene), refill jar for plastic jar with pump, 500 g
Double pack 600 g containing plastic jar (polypropylene) with pump, 500 g + plastic tube (polyethylene), 100 g, with snap cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

When using the pump jar, first remove the transport cover by pulling out the cotter and removing the collar. Press down the pump several times at the first use, in order to fill the pump.

Instructions for use for the refill jar:

- This is a refill jar. The pump from an emptied jar of Curemid is transferred to the refill jar.
- Wash your hands before changing the pump.
- First, wipe the outer parts of the pump and cover.
- Tear off the sealing ring around the lid on both the refill jar and the emptied jar with the pump (if this has not been done before).
- Remove the outer cover from the refill jar. Leave the inner lid.
- Lift the outer cover with the pump from the emptied jar. Leave the inner lid.
- AVOID touching the inside of the refill jar, the pump cover and the ascending pipe of the pump, in order not to impair the durability of the product.
- Insert the pump's ascending pipe into the hole on the inner lid of the refill jar.
- Gently press the pump into the jar until it stops. Then press firmly the edges of the outer cover properly around the entire jar.
- Check that the cover is fixed. The jar is ready to use. Pump a few times until cream comes out.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

17-06-2024