

OTC use in Norway for carbamide, ATC-code: D02AE01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing carbamide. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing carbamide. In addition, an overview of the approvable strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway is included.
- The proposed OTC indication and posology in the OTC package leaflet and labelling must be covered by the information approved in the corresponding SmPC.

Preparations for cutaneous use, up to 100 mg/g

1. Package leaflet

1.1 Indication

Til voksne og barn: fuktighetsbevarende behandling av tørr hud av ulike årsaker og til forebygging av tilbakefall ved atopisk eksem.

1.2 Posology

Voksne og barn: kremen smøres på tørr hud når du har behov. Du kan påføre kremen flere ganger om dagen, spesielt etter at huden har vært i kontakt med vann.

2. Labelling

2.1 Indication

State the indication as in the PIL.

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Not applicable.

3. Content of the pack

Pharmaceutical form	Strength	Maximum pack size
Cream	100 mg/g	500 g