

OTC use in Norway for hydrocortisone, ATC-code: D07AA02

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing hydrocortisone. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing hydrocortisone. 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 10 mg/g or 10 mg/ml

1. Package leaflet

1.1 Indication

Til voksne og barn over 2 år: behandling av mild eksem som skyldes bruk av såpe, vaskemidler og kosmetikk. Kan også brukes på insektbitt og ved solforbrenning uten sårdannelse.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml...).

Voksne og barn over 2 år: smør et tynt lag på det angrepne området av huden 2–3 ganger daglig.

Etter 3–4 dager kan du vanligvis smøre sjeldnere.

I tillegg til behandlingen med <produktnavn> bør du smøre huden flere ganger daglig med en fuktighetskrem.

Kontakt lege etter 1 ukes behandling hvis plagene blir verre eller ikke blir bedre.

2. Labelling

2.1 Indication

State the indication as in the PIL. If the full indication is stated on the back panel of the package, the following abbreviation can be used on the front panel:

Ved mild eksem.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used.

Voksne og barn over 2 år: smør et tynt lag 2–3 ganger daglig. Kontakt lege etter 1 ukes behandling hvis plagene blir verre eller ikke blir bedre.

2.3 Other information

Not applicable

3. Content of the pack

The table below presents the highest level of the terms for approvable pharmaceutical forms, if possible. For example: the term “tablets” includes all types of tablet formulations as for example film coated tablets or chewable tablets. For active substances where some pharmaceutical forms are exempt from approval due to safety concern, this is stated explicitly below the table.

Pharmaceutical form	Maximum strength	Maximum pack size
Cream, gel, ointment	10 mg/g	50 g
Solution, liniment	10 mg/ml	50 ml