

OTC use in Norway for ketoconazole, ATC-code: D01AC08

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing ketoconazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing ketoconazole. 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 20 mg/ml or 20 mg/g

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: behandling og vedlikeholdsbehandling av seboreisk eksem (dermatitt) i hodebunnen som kjennetegnes av rødhet, kløe og flass.

1.2 Posology

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

Til voksne og barn over 12 år:

1. Vask håret med vanlig sjampo og skyll godt.
2. Masser 60–100 mg godt inn i hodebunnen. Deretter venter du 3–5 minutter før du skyller håret.

Bruk <produktnavn> 2 ganger i uken i 4 uker, deretter 1 gang i uken så lenge du synes det er nødvendig.

Bruk en vanlig sjampo de dagene du ikke skal ha behandling og ønsker å vaske håret.

Kontakt lege etter 4 ukers 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:

Seboreisk eksem i hodebunnen.

2.2 Posology

State the dosage as in the PIL.

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	Strength	Maximum pack size
Shampoo, solution	20 mg/ml	120 ml
Gel	20 mg/g	120 g