

## OTC use in Norway for hydrocortisone and miconazole, ATC-code: D01AC20

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing hydrocortisone and miconazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing hydrocortisone and miconazole. 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, hydrocortisone up to 10 mg/g or 10 mg/ml and miconazole up to 20 mg/g or 20 mg/ml

#### 1. Package leaflet

##### 1.1 Indication

Til voksne over 18 år: behandling av kløende fotsopp

##### 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 over 18 år: Vask føttene og tørk godt (spesielt mellom tærne) før hver behandling. Smør soppmidlet tynt på de områdene av huden som er angrepet av sopp. Gjør dette morgen og kveld. Du bør fortsette behandlingen i omtrent 2 uker etter at soppen er borte, men behandlingen skal ikke vare lenger enn 4 uker totalt.

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:*

Kløende fotsopp

## 2.2 Posology

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

Smør soppmidlet tynt på huden morgen og kveld. Du bør fortsette behandlingen i omtrent 2 uker etter at soppen er borte, men behandlingen skal ikke vare lenger enn 4 uker totalt. 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	Strength	Maximum pack size
Cream, ointment, gel	10 mg/g hydrocortisone + 20 mg/g miconazole	20 g
Solution	10 mg/ml hydrocortisone + 20 mg/ml miconazole	20 ml