

OTC use in Norway for miconazole, ATC-code: D91AC02

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

1. Package leaflet

1.1 Indication

Til voksne og barn over 10 år: behandling av fotsopp

1.2 Posology

Voksne og barn over 10 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 i 2–6 uker. Du bør fortsette behandlingen i minst 1 uke etter at soppen er borte, men behandlingen skal ikke vare lenger enn 6 uker totalt.

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:

Fotsopp

2.2 Posology

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

Påsmøres tynt 2 ganger daglig.

2.3 Other information

Not applicable.

3. Content of the pack

Pharmaceutical form	Strength	Maximum pack size
Cream, ointment, gel	20 mg/g	30 g
Solution	20 mg/ml	30 ml