

OTC use in Norway for macrogol 4000, ATC-code: A06A D15

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing macrogol 4000. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing macrogol 4000. 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 oral use, up to 10 g per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 8 år: korttidsbehandling av forstoppelse.

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...). The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms.

Voksne og barn over 8 år: Løs opp innholdet i doseposen i et glass vann og drikk væsken. Ta 10-20 g per dag, fortrinnsvis som en enkelt dose om morgenen.

Tilpass den daglige dosen etter alvorlighetsgraden av forstoppelsen og effekten. Hos barn kan 10 g annenhver dag være tilstrekkelig.

Behandlingstiden skal ikke overskride 2 uker sammenhengende behandling. Kontakt lege etter 2 ukers sammenhengende behandling dersom plagene har blitt verre eller ikke har blitt 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:

Korttidsbehandling av forstoppelse.

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Not applicable

3. Content of the pack

Pharmaceutical form	Maximum strength	Maximum pack size
Powder or oral solution in sachet	10 g	28