

OTC use in Norway for loperamide and simethicone, ATC-code: A07DA53

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing loperamide and simethicone. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing loperamide and simethicone. 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, loperamide up to 2 mg, simethicone up to 125 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: korttidsbehandling av akutt diaré med mageknip og luftplager.

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 over 18 år: start med 4 mg/250 mg som engangsdose. Deretter tar du 2 mg/125 mg etter hver løs avføring.

Barn 12 - 18 år: start med 2 mg/125 mg som engangsdose. Deretter tar du 2 mg/125 mg etter hver løs avføring.

Ikke ta mer enn 8 mg/500 mg i løpet av 24 timer.

Hvis du fortsatt har diaré etter 48 timer må du slutte å ta legemidlet og kontakte lege.

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:

Akutt diaré med mageknip og luftplager

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Dersom du er gravid eller ammer skal du kun bruke <produktnavn> etter avtale med lege.

Ikke bruk <produktnavn> om du har høy feber (over 39 °C) eller blod i avføringen - da må du kontakte lege.

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
Tablets, capsules, oral solution in sachet	2 mg/125 mg	12