



OTC use in Norway for peppermint oil, ATC-code: A03 AX

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing peppermint oil. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing peppermint oil. 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. For **herbal preparations with well-established use the OTC indication and posology must be covered by the European Union herbal monograph on *Mentha x piperita* L., aetheroleum published on www.ema.europa.eu**

Peppermint oil preparations with a Well-established use marketing authorisation (Article 10a of [Directive 2001/83/EC](http://www.ema.europa.eu)) on the Norwegian market:

Gastro-resistant capsule, hard

182-187 mg (0.2 mL) of *Mentha x piperita* L., aetheroleum (peppermint oil).

1. Package leaflet

Indication according to national decisions:

Voksne og barn over 15 år: lindrer mageknip og luft i magen, spesielt hos pasienter med irritabel tarm-syndrom (IBS).

2. Labelling

2.1 Indication

The indication should be written as in the PIL. If the full indication is written on the back panel of the package the following short form can be used on the front panel:

Voksne og barn over 15 år: lindrer mageknip og luft i magen.

PACK SIZE

Pharmaceutical form	Strength	Maximum pack size
Gastro-resistant capsule, hard	N/A	120