

OTC use in Norway for simethicone, ATC-code: A03AX13

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing simethicone. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing 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 up to 240 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 15 år: korttidsbehandling av gass/luft som fører til smerter, oppblåsthet og ubehag i magen.

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 15 år: ta 220-240 mg 3–4 ganger daglig. Svelg <legemiddelform> sammen med et stort glass vann etter et måltid. Ikke bruk <produktnavn> i mer enn 10 dager sammenhengende.

Du må kontakte lege dersom plagene dine blir verre eller ikke blir bedre innen 10 dager.

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:

Mot oppblåsthet og luft i magen.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used. 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 og barn over 15 år: 220-240 mg 3–4 ganger daglig etter måltid. Svelg <legemiddelform> med et stort glass vann. Må ikke brukes i mer enn 10 dager sammenhengende.

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	Maximum strength	Maximum pack size
Capsule, chewable tablet, tablet, granules	240 mg	30