

OTC use in Norway for sodium alginate/sodium hydrogen carbonate/calcium carbonate, ATC-code: A02BX13

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing sodium alginate/sodium hydrogen carbonate/calcium carbonate. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing sodium alginate/sodium hydrogen carbonate/calcium carbonate. 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, sodium alginate up to 500 mg, sodium hydrogen carbonate up to 267 mg, calcium carbonate up to 325 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: lindring av sure oppstøt og halsbrann

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 12 år: Ta 1-2 doser (tilsvarende 500 mg/213 mg/325 mg eller 500 mg/267 mg/160 mg av natriumalginat/natriumhydrogenkarbonat/kalsiumkarbonat) ca. ½ time etter måltid, umiddelbart før sengetid og ved behov inntil 4 ganger daglig.

<Tygg tablettene godt før du svelger dem, <X> vil ikke virke dersom du svelger tablettene hele. Du kan dele tyggetablettene dersom du ønsker det.>

Rådfør deg med lege dersom plagene ikke er bedre eller har blitt verre etter 7 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 sure oppstøt og halsbrann.

2.2 Posology

State the dosage as in the PIL.

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
Chewable tablets or capsules Granules or oral suspension in sachets	Sodium alginate 500 mg Sodium hydrogen carbonate 267 mg Calcium carbonate 325 mg	48