Approved: 05.09.2016
Revised: 07.01.2020

Statens legemiddelverk

OTC use in Norway for alginic acid/sodium hydrogen carbonate/aluminium hydroxide, ATC-code: A02BX13

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing alginic acid/sodium hydrogen carbonate/aluminium hydroxide. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing alginic acid/sodium hydrogen carbonate/aluminium hydroxide. 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, alginic acid up to 350 mg, sodium hydrogen carbonate up to 120 mg, aluminium hydroxide up to 100 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 18 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 18 år: ta 1-3 doser (tilsvarende 350 mg/120 mg/100 mg av alginsyre/natriumhydrogenkarbonat/aluminiumhydroksid) ca. ½ time etter måltid, umiddelbart før sengetid og ved behov.
<Tygg tablettene godt før du svelger de, <X> vil ikke virke dersom du svelger tablettene hele. Du kan dele tyggetablettene dersom du ønsker det.>

For tannhelsens skyld bør du skylle munnen godt, evt. pusse tennene, etterpå.

Kontakt lege dersom du ikke har blitt bedre eller om du har blitt verre etter 2 uker sammenhengende behandling.

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	Alginic acid 350 mg Sodium hydrogen carbonate 120 mg Aluminium hydroxide 100 mg	120
Oral suspension	Alginic acid 35 mg/ml Sodium hydrogen carbonate 12 mg/ml Aluminium hydroxide 10 mg/ml	1000 ml