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Statens legemiddelverk

OTC use in Norway for sodium alginate/aluminium hydroxide/sodium hydrogencarbonate/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/aluminium hydroxide/sodium hydrogencarbonate/calcium carbonate. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing sodium alginate/aluminium hydroxide/sodium hydrogencarbonate/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 50 mg/ml, aluminium hydroxide up to 100 mg/ml, sodium hydrogencarbonate up to 17 mg/ml, calcium carbonate up to 15 mg/ml

1. Package leaflet

1.1 Indication

Til voksne 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 1-2 doser (tilsvarende 500 mg/1000 mg/170 mg/150 mg av alginsyre/aluminiumhydroksid/natriumhydrogenkarbonat/kalsiumkarbonat) ca. ½ time etter måltid, umiddelbart før sengetid og ved behov.

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
Oral suspension	1 ml contains: Sodium alginate 50 mg Aluminium hydroxide 100 mg Sodium hydrogen carbonate 17 mg Calcium carbonate 15 mg	500 ml
Chewable tablets or capsules Granules or oral suspension in sachets	Sodium alginate 500 mg Aluminium hydroxide 1000 mg Sodium hydrogen carbonate 170 mg Calcium carbonate 150 mg	50