

OTC use in Norway for calcium and cholecalciferol (vitamin D3), ATC-code: A12AX

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing calcium and cholecalciferol. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing calcium and cholecalciferol. 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, calcium up to 500 mg and cholecalciferol up to 10 microgram per unit

1. Package leaflet

1.1 Indication

Til voksne over 18 år: tilleggshandling ved beinskjørhet (osteoporose) etter at diagnosen er stilt av lege og behandlingen følges opp med regelmessig kontroll.

Til eldre over 75 år: Forebygging og behandling av kalsiummangel ved samtidig behov for vitamin D3-tilskudd.

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...).

500 mg kalsium/5 mikrogram vitamin D3

Voksne over 18 år: 500 mg/5 mikrog 1-3 ganger daglig.

500 mg kalsium/10 mikrogram vitamin D3

Voksne over 18 år: 500 mg/10 mikrog 2 ganger daglig.

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:

500 mg kalsium/5 mikrogram vitamin D3

Tilleggsbehandling ved beinskjørhet (osteoporose) etter at diagnose er stilt av lege.
Forebygging og behandling av kalsiummangel ved samtidig behov for vitamin D3-tilskudd.

500 mg kalsium/10 mikrogram vitamin D3

Tilleggsbehandling ved beinskjørhet (osteoporose) etter at diagnose er stilt av lege.
Forebygging og behandling av kalsiummangel ved samtidig behov for vitamin D3-tilskudd hos eldre over 75 år.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used.

500 mg kalsium/5 mikrogram vitamin D3

Voksne: 1 dose 1-3 ganger daglig

500 mg kalsium/10 mikrogram vitamin D3

Voksne: 1 dose 2 ganger daglig.

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
Capsules, tablets, chewable tablets	500 mg/10 microgram	100