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Statens legemiddelverk

OTC use in Norway for cholecalciferol (vitamin D3), ATC-code: A11CC05

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing cholecalciferol. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing 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, up to 20 microgram per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: forebygging av vitamin D-mangel.

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…).

Voksne og barn over 12 år: ta 10 – 20 mikrogram 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:

Forebygging av vitamin D-mangel.

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**
Capsules, tablets, chewable tablets	20 microgram	100