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Statens legemiddelverk

# OTC use in Norway for mebendazole, ATC-code: PO2CA01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing mebendazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing mebendazole. 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 mg/ml or 100 mg per unit

## 1. Package leaflet

### 1.1 Indication

Voksne og barn over 2 år: behandling av småmark.

### 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 2 år: 100 mg som engangsdose. Hele husstanden behandles. Behandlingen gjentas etter 2 uker.

## 2. Labelling

### 2.1 Indication

*State the indication as in the PIL.*

### 2.2 Posology

*State the dosage as in the PIL.*

### 2.3 Other information

Dersom du er gravid eller ammer bør behandling skje i samråd med lege.

## 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** |
|---|---|---|
| Tablets, capsules, oral suspension in sachets | 100 mg | 6 |
| Oral suspension | 20 mg/ml | 30 ml |