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Statens legemiddelverk

OTC use in Norway for ambroxol, ATC-code: R02AD05

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing ambroxol. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing ambroxol. 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 per unit or 20 mg/ml

1. Package leaflet

1.1 Indication

Voksne og barn over 12 år: lindrer smerte ved sår hals.

1.2 Posology

The quantity shall be transformed from mg to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml…) in the PIL. Include only the age group(s) for which the pharmaceutical form and strength is suitable.

Voksne og barn over 12 år: 20 mg ved behov. Maksimalt 120 mg per døgn.

Kontakt lege innen 3 dager hvis plagene blir verre eller ikke blir bedre, eller dersom du har høy feber.

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

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**
Lozenge	20 mg	18
Oromucosal spray	20 mg/ml	20 ml