



OTC USE IN NORWAY FOR AMBROXOL HYDROCHLORIDE, ATC-CODE: R05C B06

- To gain OTC prescription status for a medicinal product an application in accordance with “A guideline on changing the classification for the supply of a medicinal product for human use” should be submitted.
- This substance report presents the preferred wording for PIL and packaging material for OTC prescription status for ambroxol hydrochloride in Norway.
- To make use of this report, the application for OTC prescription status must be:
 - within the scope of what is already approved as OTC use for ambroxol hydrochloride in Norway
 - covered in the approved and/or sought SPC for the product in question

Effervescent tablet

30 mg

60 mg

Oral solution

3 mg/ml

6 mg/ml

PACKAGE LEAFLET INFORMATION

INDICATION

Voksne og barn over 6 år: korttidsbehandling av seigt slim i luftveiene.

Du må kontakte lege innen 5 dagers behandling hvis plagene blir verre eller ikke blir bedre.

DOSAGE

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.

For all pharmaceutical forms

Voksne over 18 år:

Bruk 30 mg opptil 3 ganger daglig de første 2-3 dagene. Bruk deretter 30 mg 2 ganger daglig. Du kan ved behov øke dosen til maksimalt 60 mg 2 ganger daglig.

Barn 12-17 år:

Bruk 30 mg opptil 3 ganger daglig de første 2-3 dagene. Bruk deretter 30 mg 2 ganger daglig.



Barn 6–11 år:

Bruk 15 mg opptil 3 ganger daglig.

Effervescent tablet

Brusetablettene skal løses opp i et glass vann.

Oral solution

Bruk måleredskap.

LABELLING INFORMATION

INDICATION

The indication should be written as in the PIL. If the full indication is written on the back panel of the package the following short form can be used on the front panel:

Slimløsende

DOSAGE

The dosage should be written as in the PIL.

OTHER INFORMATION

Not applicable.

PACK SIZE

Pharmaceutical form	Strength	Maximum pack size
Effervescent tablet	30 mg	20 tablets
	60 mg	10 tablets
Oral solution	3 mg/ml	200 ml
	6 mg/ml	100 ml

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