

OTC use in Norway for acetylcysteine, ATC-code: R05CB01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing acetylcysteine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing acetylcysteine. 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 600 mg per unit

1. Package leaflet

1.1 Indication

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

Du må kontakte lege innen 7 dagers behandling dersom plagene blir verre eller ikke blir bedre.

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 over 18 år: 200 mg 2–3 ganger daglig eller 600 mg en gang daglig.

Barn over 6 år: 200 mg 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:

Slimløsende

2.2 Posology

State the dosage as in the PIL. <However, the abbreviation below can be used. However, shortened if needed.

2.3 Other information

Har du astma og/eller magesår, bruk acetylcysteine kun 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
Effervescent or soluble tablets, powder or granules for oral solution, oral solution, tablets, capsules	200 mg	25
Effervescent or soluble tablets, powder or granules for oral solution, oral solution, tablets, capsules	600 mg	10