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Statens legemiddelverk

OTC use in Norway for bromhexine, ATC-code: R05C B02

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

Preparation for oral use, up to 8 mg per unit or 1.6 mg/ml

1. Package leaflet

1.1 Indication

Korttidsbehandling av seig slim i luftveiene

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: 8 mg 3 ganger daglig. Du kan ta inntil 16 mg 3 ganger daglig ved behov de første dagene.
Barn 12-18 år: 8 mg 3 ganger daglig.
Barn 6–12 år: 4 mg 3 ganger daglig.
Barn 2-6 år: 2 mg 3 ganger daglig.

Kontakt lege innen 10 dagers behandling hvis plagene blir verre eller ikke blir bedre

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.

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**
Tablets, effervescent or soluble tablets, capsules, granules	8 mg	50
Oral solution	0.8 mg/ml	125 ml
Oral solution	1.6 mg/ml	250 ml