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Revised:

Statens legemiddelverk

OTC use in Norway for lidocaine and chlorhexidine, ATC-code: R02AA05

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

Oral preparations, lidocaine up to 1 mg/unit or ml and chlorhexidine 5 mg/unit or ml

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: lindrer smerter i svelg og hals.

1.2 Posology

Lozenge (1 mg lidocaine, 5 mg chlorhexidine)
Voksne: ta 1 sugetablett hver 2.-3. time. Ikke ta mer enn 10 sugetabletter i døgnet.
Barn over 12 år: ta 1 sugetablett hver 2.-4. time. Ikke ta mer enn 5 sugetabletter i døgnet.

Oromucosal spray (0,17 mg chlorhexidine gluconate and 0,043 mg lidocaine hydrochloride monohydrate)
Voksne: ta 3-5 spray hver 2.-3. time. Ikke ta mer enn 10 spray i døgnet.
Barn over 12 år: ta 3-5 spray hver 2.-4. time. Ikke ta mer enn 5 spray i døgnet.

Kontakt lege etter 3-4 dager hvis plagene blir verre eller ikke blir bedre.

<X> skal ikke brukes sammenhengende i mer enn 5 dager. Ønsker du lenger bruk må dette avtales med lege.

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**
Lozenges	1 mg / 5 mg	36 units
Oromucosal spray	0,5 mg/ml / 2 mg/ml	30 ml