Norwegian Medical Products Agency

OTC use in Norway for lidocaine, amylmetacresol and 2,4 dichlorobenzyl alcohol, ATC-code: R02AA20

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing lidocaine, amylmetacresol and 2,4 dichlorobenzyl alcohol. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing these active substances. In addition, an overview of the approved 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.

Approved pharmaceutical form(s) and strength(s)

Oral preparations, lidocaine up to 2 mg / amylmetacresol up to 0.6 mg / 2,4 dichlorobenzyl alcohol up to 1.2 mg per unit.

1. Package leaflet

This should appear in the package leaflet:

1.1 Indication

Til voksne og barn fra 12 år: Lindrer symptomer ved sår hals.

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 etc.).

Lozenges:
Voksne: 2 mg/0.6 mg/1.2 mg hver 2.-3. time. Ikke ta mer enn 16 mg/4,8 mg/ 9,6 mg i døgnet.
Barn fra 12 år: 2 mg/0.6 mg/1.2 mg hver 2.-3. time. Ikke ta mer enn 8 mg/2.4 mg/4.8 mg i døgnet.

Sugetabletten skal løses langsomt opp i munnen. Skal ikke legges på innsiden av kinnet.

Kontakt lege etter 2 dager hvis plagene blir verre eller ikke blir bedre.

<X> skal ikke brukes sammenhengende i mer enn 3 dager.

1.3 Other information

Not applicable

2. Labelling

This should appear on the labelling:

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2.1 Indication

State the indication as in the PL.

2.2 Posology

State the dosage as in the PL.

2.3 Other information

Dette legemidlet anbefales ikke til gravide eller ammende.
Skal ikke brukes hos barn under 12 år.

3. Content of the pack

Approved strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway:

Pharmaceutical form	Maximum strength	Maximum pack size
Lozenges	2 mg/0.6 mg/1.2 mg	24

Approved date

Approved: 30.10.2024