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:
Lozenges containing lidocaine up to 2 mg / amylmetacresol up to 0.6 mg / 2,4-dichlorobenzyl alcohol up to 1.2 mg per unit.
Oromucosal spray containing lidocaine up to 6 mg/ml / amylmetacresol up to 2.23 mg/ml / 2,4-dichlorobenzyl alcohol up to 4.46 mg/ml.

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

The text below represents the posology and the necessary information included for the most commonly used pharmaceutical dose forms.

Lozenges (2 mg lidocaine, 0.6 mg amylmetacresol, 1.2 mg 2,4-dichlorobenzyl alcohol per unit):
Voksne: 1 sugetablett hver 2.-3. time. Ikke ta mer enn 8 sugetabletter i døgnet.
Barn fra 12 år: 1 sugetablett hver 2.-3. time. Ikke ta mer enn 4 sugetabletter i døgnet.

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

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

Oromucosal spray (0.78 mg lidocaine, 0.29 mg amylmetacresol, 0.58 mg 2,4-dichlorobenzyl alcohol per pump actuation):
Voksne og barn fra 15 år: En dosering på 2 sprayer bak i svelget 1-6 ganger i døgnet.
Barn 12–15 år: En dosering på 2 sprayer bak i svelget 1-4 ganger i døgnet.

Det bør gå minst 2 timer mellom hver dosering.

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<X> skal ikke brukes sammenhengende i mer enn 5 dager.

All pharmaceutical dose forms:
Ikke ta dette legemidlet rett før måltider eller før du drikker.
Kontakt lege etter 3 dager hvis plagene blir verre eller ikke blir bedre.

1.3 Other information

Not applicable

2. Labelling

This should appear on the labelling:

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 units
Oromucosal spray	6 mg/ml / 2.23 mg/ml / 4.46 mg/ml	20 ml

Approved date

Approved: 13.12.2024

Revision history:
13.12.2024: Inclusion of oromucosal spray and updated indication, posology and labelling.
12.02.2019: First version approved.

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