

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

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing amylmetacresol and 2,4-dichlorobenzyl. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing amylmetacresol and 2,4-dichlorobenzyl. 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, amylmetacresol up to 0.6 mg and 2,4-dichlorobenzyl alcohol up to 1.2 mg

1. Package leaflet

1.1 Indication

Til voksne og barn over 6 år: lindrer smerter i svelg og 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...). Include only the age group(s) for which the pharmaceutical form and strength is suitable.

Voksne og barn over 6 år: 0,6/1,2 mg hver 2.-3. time.

Barn 6-11 år: Maksimalt 2,4/4,8 i døgnet.

Voksne og barn over 12 år: Maksimalt 4,8/9,6 mg i døgnet.

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

<Produktnavn> 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 | 0.6 mg amylmetacresol and 1.2 mg 2,4- dichlorobenzyl per unit | 24 |
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