

OTC use in Norway for benzydamine, ATC-code: R02AX03

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing benzydamine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing benzydamine. 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, up to 3 mg or 3 mg/ml

1. Package leaflet

1.1 Indication

Til voksne og barn over 6 år: lindrer smerter i munn, 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...). The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms

Solid formulations

Voksne og barn over 6 år: 3 mg inntil 3 ganger daglig. <For å oppnå maksimal effekt skal sugetabletten smelte langsomt i munnen. Sugetabletten skal ikke svelges hel eller tygges.>

Liquid formulations

Voksne og barn over 12 år: Inntil 2 mg hver 1 ½-3 time.

Barn 6-12 år: Inntil 1 mg hver 1½-3 time.

Kontakt lege innen 3 dager hvis plagene blir verre eller ikke blir bedre. <X> skal ikke brukes sammenhengende i mer enn 7 dager.

Ta aldri mer enn den anbefalte dosen uten å ha rådført deg med lege.

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:

Smertelindrende ved sår hals.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used.

Solid formulations

Voksne og barn over 6 år: 1 sugetablett inntil 3 ganger daglig. Tabletten skal smelte langsomt i munnen. Tabletten skal ikke svelges hel eller tygges.

Liquid formulations

Voksne og barn over 12 år: Inntil 2 mg hver 1½ - 3 time. Barn 6-12 år: Inntil 1 mg hver 1½ - 3 time.

Når barn tar <produktnavn>, bør en voksen kontrollere at medisinen tas korrekt.

Kontakt lege innen 3 dager hvis plagene blir verre eller ikke blir bedre.
<Produktnavn> skal ikke brukes sammenhengende i mer enn 7 dager.

2.3 Other information

Not applicable.

3. Content of the pack

Pharmaceutical form	Maximum strength	Maximum pack size
Lozenges	3 mg	24
Oromucosal spray	3 mg/ml	30 ml