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Statens legemiddelverk

OTC use in Norway for flurbiprofen, ATC-code: R02AX01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing flurbiprofen. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing flurbiprofen. 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 8.75 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: lindring av ubehag 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…).

Voksne og barn over 12 år: 8,75 mg hver 3.-6. time, maksimalt 45 mg per døgn.

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 legen.

<For å oppnå maksimal effekt skal sugetabletten smelte langsomt i munnen. Sugetabletten skal ikke svelges hel eller tygges.>

2. Labelling

2.1 Indication

State the indication as in the PIL.

2.2 Posology

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

Voksne og barn over 12 år: 8,75 mg hver 3.-6. time, ikke mer enn 45 mg per døgn.

<Sugetabletten skal smelte langsomt i munnen. Sugetabletten skal ikke svelges hel eller tygges.>
Kontakt lege innen 3 dager hvis plagene blir verre eller ikke blir bedre.
<X> skal ikke brukes sammenhengende i mer enn 7 dager.

2.3 Other information

Skal ikke brukes dersom du er overfølsom overfor acetylsalisylsyre eller andre legemidler mot feber, smerter eller betennelse. Skal ikke brukes av gravide og ammende.

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**
Lozenge	8.75 mg	16
Oromucosal spray	8.75 mg	15 ml