

OTC use in Norway for ranitidine, ATC-code: A02BA02

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing ranitidine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing ranitidine. 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, ranitidine up to 75 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 16 år: korttidsbehandling av halsbrann og sure oppstøt.

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 over 16 år: ta 75 mg ved behov. Du må ikke ta mer enn 150 mg i løpet av 24 timer.

Kontakt lege etter 2 ukers sammenhengende bruk dersom plagene har blitt verre eller ikke har blitt bedre.

Kommer plagene ofte tilbake er det viktig at du kontakter 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:

Mot halsbrann og sure oppstøt.

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Dersom du er gravid eller ammer skal du kun bruke <X> etter avtale med lege.

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	Strength	Maximum pack size
Tablets, effervescent tablets, capsules, granules	75 mg	24