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Statens legemiddelverk

OTC use in Norway for omeprazole, ATC-code: A02BC01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing omeprazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing omeprazole . 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 use, omeprazole up to 20 mg per unit

1. Package leaflet

1.1 Indication

Til voksne over 18 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…). The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms

Voksne over 18 år: ta 10–20 mg 1 gang daglig. Ta <produktnavn> før et måltid, til samme tidspunkt hver dag. Du skal svelge <produktnavn> hel med litt vann. Ikke tygg eller knus <produktnavn>. Ta ikke mer enn 20 mg i løpet av 24 timer.
Noen ganger er det nødvendig å ta <produktnavn> i 2–3 dager før du merker bedring.

Kontakt lege dersom du ikke har blitt bedre eller om du har blitt verre etter 2 uker sammenhengende behandling.
Kommer plagene raskt eller ofte tilbake er det viktig at du kontakter lege.
<Produktnavn> skal ikke brukes sammenhengende i mer enn 4 uker. Ønsker du lenger bruk må dette avtales 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:

Mot halsbrann og sure oppstøt

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
Gastro-resistant tablets, capsules or granules	10 mg	28
Gastro-resistant tablets, capsules or granules	20 mg	14