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Statens legemiddelverk

OTC use in Norway for pantoprazole, ATC-code: A02BC02

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing pantoprazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing pantoprazole. 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, pantoprazole 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 20 mg daglig til samme tidspunkt og før et måltid. Du skal svelge <produktnavn> hel med litt vann. Ikke tygg eller knus <produktnavn>.
Noen ganger er det nødvendig å ta <produktnavn> i 2–3 dager før du merker bedring.

Kontakt lege etter 2 ukers sammenhengende bruk dersom plagene har blitt verre eller ikke har blitt bedre.
<Produktnavn> skal ikke brukes sammenhengende i mer enn 4 uker. Ønsker du lenger bruk må dette avtales med lege.
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
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	20 mg	14