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Statens legemiddelverk

OTC use in Norway for dimenhydrinate, ATC-code: R06AA02

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

1. Package leaflet

1.1 Indication

Til voksne og barn over 6 år: reisesykemiddel som motvirker kvalme og brekninger.

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: Ta 20-40 mg 1-2 timer før avreise. Du kan ta en ny dose etter 6-8 timer. Ikke ta mer enn 140 mg i løpet av 24 timer.

Barn/ungdom 12-17 år: Ta 20-40 mg 1-2 timer før avreise. Du kan ta en ny dose etter 6-8 timer. Ikke ta mer enn 80 mg i løpet av 24 timer.

Barn 6–11 år: Gi 20 mg 1-2 timer før avreise. Du kan gi en ny dose etter 6-8 timer. Ikke gi mer enn 60 mg i løpet av 24 timer.

Pasienter med leversykdom eller nedsatt leverfunksjon: Ta 20-40 mg 1-2 timer før avreise. Du kan ta en ny dose etter 6-8 timer. Ikke ta mer enn 80 mg i løpet av 24 timer.

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:

Reisesykemiddel

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**
Lozenge	20 mg	24

** Each new pharmaceutical formulation of dimenhydrinate applied for as OTC-product must be assessed due to the risk of abuse of certain formulations and strengths.*